PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 1/12

A1

(11) International Publication Number: **WO 98/55165**

(43) International Publication Date: 10 December 1998 (10.12.98)

(21) International Application Number: PCT/AU98/00433

(22) International Filing Date: 9 June 1998 (09.06.98)

(30) Priority Data:
PO 7231 6 June 1997 (06.06.97) AU

(71)(72) Applicants and Inventors: WOODARD, John, C. [AU/AU]; 27 Wareemba Avenue, Thornleigh, NSW 2120 (AU). SEARE, William, J., Jr. [US/US]; 3190 Chula Vista Circle, Salt Lake City, UT 84121 (US).

(74) Agent: DUMMER, Peter, C.; 12 Clarke Street, Rydalmere, NSW 2116 (AU).

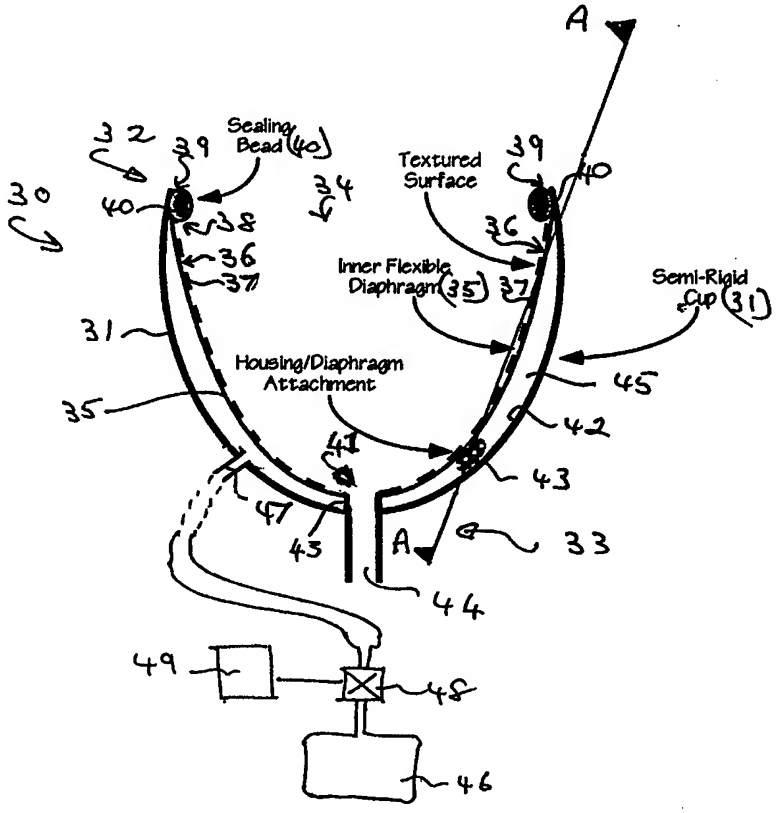
(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
With amended claims.

(54) Title: CARDIAC ASSIST DEVICE

(57) Abstract

A cardiac assist device (30) including (a) a cup or like device (31) adapted to receive at least ventricular portions of a heart muscle therein; (b) within the cup (31), a diaphragm member (35) including a cardiac tissue contacting surface (36) having a biointegrating membrane (37) or layer by which at least portions of the diaphragm member (35) become biointegrated with the cardiac tissue; (c) a pneumatic chamber defined between at least a portion of the cup (31) and a portion of the diaphragm member whereby relative positive and negative pressures can be alternately induced in the pneumatic chamber so as to cause, respectively, compression and distension of at least portions of the heart muscle so as to at least assist systole and diastole of the heart muscle. In a particular form the biointegrating membrane or layer (37) comprises a plurality of strips (52) of biointegrating material attached to or forming part of the diaphragm member and separated by portions of the diaphragm member having no biointegrating material.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

CARDIAC ASSIST DEVICE

The present invention relates to a cardiac assist device and, more particularly, to such a device incorporating biointegrating materials and to a method of attachment of the device to a heart.

DISCUSSION OF PRIOR ART

Cardiac assist devices of various kinds are known, all of which have the aim of at least being able to apply periodic pressure to the exterior of the heart muscle so as to assist the pumping action of the heart muscle. Certain forms of these devices have the ability to also apply a pulling or distraction force to the exterior of the heart muscle so as to assist diastole.

A particular form of such a device is disclosed in US 3455298 to Anstadt.

In substance, with reference to Fig. 1, Anstadt discloses a direct cardiac compression ventricular assist device 10 comprising a resilient cup 11 inside which is disposed a flexible diaphragm 12. The ventricular portions 13 (being the lower portions) of a heart muscle 14 sit within the device 10 as generally illustrated in Fig. 1.

A vacuum is applied between the diaphragm 12 and the ventricular portions 13 by way of vacuum line 15 and auxiliary vacuum line 16. A sufficient vacuum is applied so as to induce effective attachment of diaphragm 12 to the surface 21 of the ventricular portions 13 of heart muscle 14, such that significant compression and distending forces can be applied to the diaphragm 12 (and hence heart muscle

14) without the diaphragm 12 coming away from the ventricular portions 13.

The diaphragm 12 is sealed circumferentially by a top circumferential seal 17 to the cup 11 and at a lower circumferential seal 18 to the cup 11 so as to define an operating chamber 19 located therebetween.

The chamber 19 is in pneumatic communication with a pneumatic operating line 20 whereby positive air pressures can be applied to the operating chamber 19 so as to cause systole and, alternatively, vented to ambient air to allow passive filling or a vacuum can be applied so as to cause diastole.

A major operational concern with this prior art arrangement is that loss of vacuum from vacuum line 15, even if only temporary, causes separation (usually ejection during positive air pressure application) of heart muscle 14 from the device 10, with life threatening consequences.

It is an object of the present invention to overcome or substantially ameliorate this problem in the context of cardiac assist devices.

In addition, two lines, one for enabling the diastole-systole of pumping and another for suction requires two exit sites or a larger exit site for two tubes providing for both suction and driving pressure. In addition, the communication with this vacuum line from the surface of the heart to the dead space of the vacuum line which is in communication with the outside creates two very poor situations.

1. The first is that this communication with the heart surface to the outside provides a potential source for infection from the outside to the surface of the heart. Communicating with the vacuum must be sterile. Even though suction is to the outside, bacteria are well known to be able to migrate retrograde on surfaces, such as vascular grafts, against the flow to contaminate with bacterial biofilm on the entire surface.

2. The second is that bacteria thrive on surfaces where the tissue of the body, and specifically the body's cellular defence mechanisms of the white cell and T-killer cells cannot be mobilised. The interior surface of the vacuum tube is an excellent dead space without opposing tissue and therefore there are no available cellular defence mechanisms to control the bacteria and the biofilm in this location. Where the pumping driveline system is not in continuity with the body (because it is isolated from the body and therefore pressurizable (except where there may be a failure, leakage, or otherwise breakdown of the pumping system) of the body, the suction system is.

This may be one of the major reasons of the failure of the Anstadt device even short term and why infection problems have been experienced. It is therefore, another object of at least some embodiments of the present invention to use no suction assist to keep the assist device in place, or to use very short term suction until biointegration is complete and then removing it.

Relevant art includes US3464322, US3587567, US3613672, US4536893, US4690134, US4957477, US5098369, US5131905 which

provides an overview of cardiac assist device technology as well as disclosing particular approaches. Mention is made that there can be problems with compatibility as between the living tissue of the human body and the materials from which the assist devices are made.

It is a further object of the present invention to provide a method of attachment of an assist device to exterior portions of a heart muscle which minimises, or at least manages, compatibility and rejection issues.

BRIEF DESCRIPTION OF THE INVENTION

Accordingly, in one broad form of the invention there is provided a method of attachment of a cardiac assist device to the heart; said cardiac assist device of the type including a member adapted for relative periodic shape change so as to apply a periodic generally inwardly directed force to ventricular portions of a heart thereby to assist systole of said heart;

said method comprising:

attaching a biointegrating membrane to at least a portion of said member which is in contact with an exterior surface of said heart;

causing said biointegrating membrane to attach to said exterior surface of said heart whereby said member becomes attached to said heart.

Preferably said member is further adapted to apply a periodic generally outwardly directed force to said ventricular portions of said heart thereby to assist dyastole of said heart.

Preferably said member is a diaphragm member located within and adapted to act against a cup or like resilient support structure.

Preferably said biointegrating membrane is in the form of strips of biointegrating material separated by zones of non-biointegrating material.

In one preferred form said strips are applied radially to said heart.

In an alternative preferred form said strips are applied longitudinally to said heart.

Preferably said zones of non-biointegrating material are smooth and flexible so as to allow relative movement of said strips during use.

In a particular preferred form said strips are applied both radially and longitudinally to said member so as to define a plurality of isolated zones of non-biointegrating material.

In one preferred form said biointegrating membrane is made by the Replamineform process.

In an alternative preferred form said biointegrating membrane is made by the process of utilising at least one removable open-cell porous mould form comprising particles formed and shaped into a solidified mass of continuously interconnected particles defining continuously interconnected pores and connecting interstices.

In a further broad form of the invention there is provided a cardiac assist device for attachment to a heart in accordance with the above described method.

In yet a further broad form of the invention there is provided a cardiac assist device including

(a) a cup adapted to receive at least ventricular portions of a heart muscle therein

(b) within said cup, a diaphragm member including a cardiac tissue contacting surface having a biointegrating membrane or layer by which at least portions of said diaphragm member become biointegrated with said cardiac tissue.

(c) a pneumatic chamber defined between at least a portion of said cup and a portion of said diaphragm member whereby relative positive and negative pressures can be alternately induced in said pneumatic chamber so as to cause, respectively, compression and distension of at least portions of said heart muscle so as to at least assist systole and diastole of said heart muscle.

Preferably said biointegrating membrane or layer comprises a plurality of strips of biointegrating material attached to or forming part of said diaphragm member and separated by portions of said diaphragm member having no biointegrating material.

Preferably said diaphragm member is caused to be attached to said cardiac tissue in a manner such that involution occurs during systole of said portions of said diaphragm member having no biointegrating material.

Preferably said cup is of substantially ellipsoid shape in cross section.

Preferably said biointegrating membrane or layer is applied in a pattern to said diaphragm member that allows

i. drainage of initial serous fluid to a temporary port

ii. passage of the coronary vessels without compression and

iii. controlled folding of the diaphragm member during inflation.

Preferably said biointegrating membrane or layer is arranged so as to develop vascularity thereby to improve infection resistance.

Preferably said diaphragm member varies in thickness and conformation so as to enhance sequential compression of the right ventricle and left ventricle.

Preferably initial attachment of said diaphragm member to said heart muscle is assisted by use of a tissue glue.

Preferably the continuous cyclic pressure of systole-diastole assists in biointegration of the cardiac tissue contacting porous surfaces of said biointegrating membrane.

Preferably the cardiac assist device is installed according to the following steps:

a. Initially no negative vacuum is used to assist the natural heart filling.

b. Further pressure of systole then inwardly involutes the smooth folding strips, causing the relatively more rigid biointegrating porous sections to come together, but also forcing the heart to contract, both at the biointegrating porous sections and the smooth folding strips.

Preferably said strips of biointegrating material are aligned in annular fashion about said diaphragm member.

In an alternative preferred form said strips of biointegrating material are aligned in longitudinal fashion about said diaphragm member.

Preferably said diaphragm member is treated with a lubricating substance in order to assist movement of those portions of said diaphragm member not having biointegrating material thereon relative to said heart muscle.

Preferably a tube communicates from said heart muscle to exterior said cup and acts as a conduit for vacuum and for fluid draining.

Preferably said diaphragm member includes more than one layer with a lubricant disposed between adjacent layers.

Preferably relatively more rigid biointegrating porous sections come together as they force the surface of the heart to contract (either totally assisted or partially assisted) whereby motion is created within the elastic matrix of the epicardium and heart muscle themselves, requiring no shearing at the biointegrating porous sections-tissue interface itself thereby to assist biointegration.

Preferably systolic pressure and the vacuum of the holding system and resultant relative micromotion between the heart and the porous material act together to speed and aid biointegrating mechanisms as the heart is forced to contract and act to pull amounts of blood and serum into

the interstices of the biointegrating porous sections which act as a scaffold for biointegration.

Preferably seroma or haematoma formation between the heart and the biointegrating porous sections are gently massaged away and either into the biointegrating porous sections or away into the draining function of both at the biointegrating porous sections and the smooth folding strips.

In a particular preferred form controlled folding is induced in the diaphragm whereby a plurality of independently operable pneumatic or hydraulic chambers are created.

In a further particular preferred form the cup is opened at both its base and its apex.

In a further particular preferred form the arrangement is such that differential urging of the right and left ventricles of the heart is induced. More preferably the urging is proportional to the displacement of the separate pneumatic chambers generated by the controlled folding action.

Preferably said membrane is assisted in its attachment with low vacuum or intermittent vacuum.

Preferably said membranes are assisted in its attachment by reducing its motion on the ventricle myocardium by suturing the apex and the base to the heart with the use of a suturing cuff.

Preferably said member can apply diastolic force after biointegration without the necessity of continuous suction.

In another preferred form, said strips are applied longitudinally to said heart.

Preferably said zones of non-biointegrating material of the diaphragm are fixed to the resilient support structure to thereby control the folding.

Preferably said diaphragm member-cup member attached units are of different widths so that during inflation of the created pneumatic chamber, displacement into the myocardium is controlled.

Preferably the width and number of thus created pneumatic chambers is controlled such that differential displacement of the pneumatic chamber into the right ventricle is less than into the left ventricle, thereby differentially pumping the right and left ventricles.

Preferably the short term continuous suction assists in biointegration of the cardiac tissue.

In an alternative form the short term intermittent suction assists in biointegration of the cardiac tissue.

In an alternative preferred embodiment, the smooth folding strip's inward involutional section is attached to the resilient cup so as to specifically control the folding and create a separate pneumatic chamber.

Preferably draining is performed:

a. where said tube is a plurality of tubes

b. where said tube(s) are designed into the device to be removable, when they are no longer necessary.

c. where said tube(s) and the resultant vacuum and fluid drainage communicate with the interconnected pores of the biointegratable material such that

i. more efficient removal of accumulated fluid.

ii. more effective vacuum holding power of the biointegratable material to the myocardial surface occurs.

iii. closer coadaptation of the material to the myocardium occurs so that quicker and more efficient biointegration occurs.

d. where said tubes communicate with each biointegratable strip.

BRIEF DESCRIPTION OF DRAWINGS

Embodiments of the invention will now be described with reference to the accompanying drawings wherein:-

Fig. 1 is a side, partly sectioned view of a prior art direct cardiac assist device,

Fig. 2 is a side section view of a cardiac assist device according to a first embodiment of the invention,

Fig. 3 is an electron micrograph of a porous material suitable for use with the device of Fig. 2,

Fig. 4 is a section, cutaway view of the material of Fig. 3 as applied to the diaphragm member of the device of Fig. 2,

Fig. 5 is a block diagram of a control system arrangement suitable to control and power the device of Fig. 2,

Fig. 6 is a side section view of a cardiac assist device according to a second embodiment of the invention,

Fig. 7 illustrates a cardiac assist device according to a third embodiment of the invention,

Fig. 8 illustrates behaviour of the diaphragm member of the device of Fig. 7 during diastole,

Fig. 9 illustrates behaviour of the diaphragm member of the device of Fig. 7 during systole, and

Fig. 10 is a side section view of a cardiac assist device according to a fourth embodiment of the invention.

Fig. 11 is a side section view of a cardiac assist device according to a fifth embodiment of the invention,

Fig. 12 is a side, partly sectioned view of interior portions of a cuff portion of the device of Fig. 11,

Fig. 13 is a perspective view of a drive line arrangement for a direct cardiac assist device according to a further embodiment of the invention.

Fig. 14 is a cross-section through a mid portion of the device of Fig. 12 with the corset open.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

With reference to Fig. 2 a cardiac assist device 30 adapted to perform functions similar to the assist device described with reference to Fig. 1 is illustrated in side section view. It comprises a cup 31 of resilient material and of generally parabolic side cross section with the open ends of the paraboloid terminating in a cup base 32 and the apex of the paraboloid defining a cup apex 33. The cup 31 is sized so as to accept comfortably at least the lower, ventricular portions of a heart muscle 14 as for the prior art device of Fig. 1.

In this embodiment the interior 34 of cup 30 houses a diaphragm member 35. The inner surface 36 of diaphragm member 35 has a surface modification which includes at

least portions of a biointegrating material 37 as will be further described with reference to Figs. 3 and 4.

The diaphragm member 35 is substantially conical in overall shape with its base portion 38 of substantially the same diameter as the cup base 32 thereby facilitating the sealing of the base portion 38 of diaphragm member 35 against an inside lip 39 of cup base 32 by, in this embodiment, a sealing bead 40.

In addition, in this embodiment, the diaphragm member 35 is attached near its apex 41 to interior surface 42 of cup 31 at an annular point of attachment 43.

In this instance the opportunity is taken for a vacuum port 44 to pass through or within the area circumscribed by annular point of attachment 43 at at least one point whereby the interior 34 of cup 31 is placed in vacuum communication with the exterior of cup 31 as illustrated in Fig. 2.

The vacuum port 44 allows a vacuum to be applied as between the inner surface 36 of diaphragm member 35 and the surface 21 of at least ventricular portions of heart muscle 14 (not shown, but in the same manner as performed by vacuum line 15 in respect of the arrangement of Fig. 1 previously described).

In addition vacuum port 44 can also perform drainage functions as to be later described.

A pneumatic chamber 45 defined between diaphragm 35 and interior surface 42 of cup 31 is in pneumatic communication with an external pneumatic source 46 via

drive port 47 and valve system 48 and controlled by pneumatic control system 49.

The pneumatic source 46, via valve system 48, can deliver positive pressure into pneumatic chamber 45 so as to cause diaphragm member 35 to exert a compressive force on at least the ventricular portions 13 within heart muscle 14 so as to eject blood from the ventricle. Conversely, and alternately, the pneumatic source 46, via valve system 48 can communicate a negative pressure via drive port 47 to pneumatic chamber 45 thereby causing diaphragm 35 to move towards interior surface 42 of cup 31 whereby a distending force is applied to at least the ventricular portions 13 of a heart muscle 14 so as to induce filling of the heart ventricles with blood.

In the arrangement illustrated in Fig. 2 the ability of the diaphragm member 35 to exert the necessary systolic and diastolic pressures depends firstly on sufficient rigidity of cup 31 and secondly upon suitable attachment of inner surface 36 of diaphragm member 35 to at least sufficient portions of the ventricular portions 13 of heart muscle 14 so that the necessary compressing and distending forces will be applied to the heart muscle 14.

Sufficient rigidity of the cup 31 is, for example, provided by materials such as polyurethanes and silicones with sufficient stiffness and thickness to prevent collapse during the vacuum (diastolic) cycle.

In this embodiment appropriate and sufficient attachment of inner surface 36 of diaphragm member 35 to at least portions of the ventricular portions 13 of heart

muscle 14 are provided by a biointegrating material 50 of the type exemplified by Fig. 3 arranged in an alternating stripped pattern 51 as generally illustrated in Fig. 4.

In this embodiment the biointegrating material is silicone rubber provided by Dow Corning, of Q7-4860, and includes the biointegrating structure described in US Patent Number 5,605,693 dated Feb. 25, 1997, which patent is incorporated herein by cross-reference.

US5,605,693 to one of the present inventors is directed to methods of making a porous device utilising at least one removable open-cell porous mould form comprising particles formed and shaped into a solidified mass of continuously interconnected particles defining continuously interconnected pores and connecting interstices. The primary mould form is made from a selected material comprising particles having predetermined sizes and shapes which is capable of forming a stable mould form under selected conditions and of being removed under selected conditions. The primary mould form can be used to mould a porous device directly or to mould a secondary mould form. Similarly, the secondary mould form can be used to mould a porous device directly or to mould a tertiary mould form. Depending on the number of mould forms used, the porous device contains pores and pore interconnections corresponding to either the continuously interconnected particles, or to the continuously interconnected pores.

Fig. 4 comprises section AA through the device 30 of the first embodiment illustrated in Fig. 2. It shows a preferred pattern of biointegrating material 37, in this

instance as illustrated in Fig. 4, laid down as an alternating stripped pattern 51. In this instance biointegrating material 50 is laid down in annular strips 52 of width D separated from one another by annular interrupting surfaces 53 of width d. In the limit at apex 41 the strip 52 degenerates to a disk structure.

In this embodiment a preferred range for dimension D is 2mm to 4cm with a more preferred range being 5mm to 15mm. In this embodiment a preferred range for dimension D is 2mm to 4cm with a more preferred range being 5mm to 15mm.

In use, temporary vacuum port 44 communicates a vacuum to interior 34 of cup 31 at time of initial installation of cardiac assist device 30 and for a predetermined period thereafter sufficient to allow biointegrating material 50 to integrate with the surface of heart muscle 14 to the extent that vacuum is no longer required to prevent separation of diaphragm 35 from the heart muscle surface during operation of the cardiac assist device 30.

This predetermined period typically ranges from several days to fourteen days after initial implantation.

The first several days to one week serves a dual purpose to allow for the removal of blood and serum accumulating on the epicardial surface of the heart. Not only are these prone to infection, but they also may retard the heart surface from biointegrating into the biointegrating surface 37.

In another embodiment of the present invention, the temporary vacuum port or ports are designed to be

removable, since after biointegration they are no longer necessary, and their removal eliminates a potentially open passage from the surface of the heart to the exterior, and also eliminates the dead space within port 44 where bacteria and bacterial biofilms can grow in an area without tissue contact and therefore without the body's cellular defence system and therefore would constitute functional immunosuppression in that the white cells could not function against the bacterial contamination. This removability creates an open end in this apex, as already described. In yet another embodiment, the annular point of attachment of 43 of the cup to the diaphragm which allows passage of the vacuum tube(s) 44, could have a sewing ring of a polyester (Dacron) velour, felt or weave or other suitable fabric material attached to allow temporary suture fixation of the apex of the cardiac assist device to the apex of the heart. This would stabilise the apex of the heart to the assist device and allow the vacuum tube(s) 44 to be removed without undue displacement of the heart and the biointegrated material from occurring. In addition, an appropriate fabric sewing ring can also be attached to the base at 39 or 40 for similar temporary fixation and stability.

As previously described the heart muscle 14 is assisted to achieve blood ejection by application of a positive pressure in pneumatic chamber 45 and filling by application of a negative pressure in pneumatic chamber 45.

One example of a control system to achieve the necessary application of pneumatic pressures is illustrated

in Fig. 5 and comprises a valve system 48 adapted to communicate pneumatic pressures from external pneumatic source 46. More specifically valve system 48 comprises a dual proportional valve 54 with valve regulator 55.

First valve 56 is adapted to communicate positive pressures from positive pressure source 57 to drive port 47 whilst second valve 58 is adapted to communicate negative pressures from negative pressure source 59 to drive port 47.

A pneumatic profiler 60 provides a reference waveform for actuation of the valve system 48. The combination of pneumatic profiler 60 and proportional valves within valve system 48 permit good control with respect to time of both magnitude and sign of pressure within pneumatic chamber 45 and hence of compression and distension forces applied to heart muscle 14. The ability to control these forces variably with respect to time provides an extra control parameter for assistance of both systole and diastole of heart muscle 14.

A further control parameter can be introduced by separating pneumatic chamber 45 into a number of independently controllable subregions as generally illustrated in cross section in the second embodiment of Fig. 6.

With reference to Fig. 6 a cardiac assist device 61 according to a second preferred embodiment of the invention is illustrated in cross section with like components numbered as for the first embodiment previously described.

In this instance pneumatic chamber 45 is subdivided into separate, independent pneumatic chambers comprising first annular chamber 62, second annular chamber 63, third annular chamber 64 and fourth annular chamber 65.

Fig. 6 further illustrates the use of multiple drivers 48A-F of the type 48 described with reference to Fig. 5 and co-ordinated by an area profiler 66 which permits the application of separate and different pressure versus time profiles to different portions of the heart muscle 14.

In addition in this instance membrane 35 comprises a first membrane 35A and a second membrane 35B arranged so as to define a cavity between the two membranes 35A, 35B which accepts a lubricant 73 such as graphite or silicone oil so as to inhibit creasing or folding of the myocardial tissue attached to membrane 35. This arrangement has particular function during compression (systole). The addition of lubricants between the two membranes 35A and 35B also contributes to increasing the flex life of both membranes.

Fig. 7 illustrates a third embodiment of the cardiac assist device 70 incorporating the following features and characteristics.

The third embodiment includes a refined inner flexible diaphragm member 74.

The preferred device 70 of the third embodiment includes alternating longitudinally oriented strips of biointegrating porous sections 71, followed by smooth folding sections 72. As few as two of each, up to several dozen may be employed in different configurations or patterns to attain the desired combinations of specific

folding, size variation, compliance and removability. In a device such as a direct cardiac compression cup, there are advantages for these strips to have differing geometries to accomplish differing aims of the combinations listed above.

For illustrative purposes, the exemplary design of this embodiment is called an internally (on the fluid containing side) fluted goblet design. In the fluted goblet design, the longitudinal flutes correspond to smooth folding sections of the cup. The flutes run longitudinally from the stem section of the goblet (Anstadt's apex) to its mouth (Anstadt's base) and extend away from the inner surface of the goblet. In this embodiment the folding sections run from the apex of the heart (stem) to the base (mouth) and extend away from the epicardial surface as seen in Section BB in Fig. 7. The non-fluted or uncut crystal sections of the goblet correspond to the biointegrating, porous sections which alternate with the folding sections. In this design, there are at least two folding sections separating two biointegrating sections between them.

In alternative embodiments up to many dozen folding sections (flutes) may be present separating the biointegrating (non-fluted) sections. In both analogies, the uncut or non-folding sections are the thicker, relatively rigid and non-folding compared to the flutes or folding sections. The folding sections (flutes) on the other hand, are thin, and comprise discontinuations between the thicker, more durable sections. In the fluted goblet example, the uncut or non-fluted sections are generally wider in dimension than the fluted sections, and to

compensate for the spherical shape, are wider at the greatest circumference, tapering or narrowing proportionally to the decreasing circumference at the top of the mouth (or base) and the bottom of the goblet (or apex). The tapering from the equator, may be accomplished in the flutes (folding sections), in the uncut (biointegrating sections) or a combination of the two.

This arrangement allows for the thickness of the porosity and the need for relative non-movement of the porous sections upon the epicardium, while and after biointegration has taken place. The inverting folds allow for the dynamic changes in shape of the diaphragm member 74 which will occur during active pumping and for longer term changes of the end diastolic heart size from disease to recovery.

In this example, the uncut sections cannot overlap (negative space). In the diaphragm member 74, the biointegrating sections are attached to the surface of the heart and overlap of any significance is counter-productive and tends to displace the biointegration from its attachment to the heart 14. In a preferred arrangement the biointegrating sections 71 and smooth folding sections are arranged such that the sections 71 are apart or just come together at maximum systole at the minimum or healthy heart volume as depicted in Fig. 9. Any further decrease in outer surface area and inner volume tends to displace the strips. During diastole with the largest heart volume, the grooves unfold to their maximum volume- surface area, to

expose all of smooth surfaced parts 72 of the diaphragm at the heart surface as depicted in Fig. 8.

In practice, the cardiac assist device 70 of the third embodiment comprises an outer rigid diaphragm housing or cup 75 with a vacuum port 44 and an integrally connected driveline, a drive port 47 and the diaphragm member 74 attached. The base does not extend onto or interfere with the atria or the great vessels. Some sizing is required, but the need for this is minimised with this design since controlled folding of the smooth folding sections 72 easily accommodates the application of an oversized inner flexible diaphragm 74, to a smaller heart.

The device 70 is introduced onto the heart by cycling the driver 46, 48, 49 into full diastole, with vacuum to cause the diaphragm member to become applied to the inside the cup 75. Thus, the inside membrane volume or size is maximised. The dimensions are the internal dimensions of the cup 75 less any thickness of the diaphragm member 74, with its included porosity. This in general causes the inner membrane dimensions to be several millimetres smaller than the internal dimensions of the cup 75. A separate low pressure continuous vacuum through the vacuum port 44 is then applied as the assembly is slid onto the heart. Once a partial seal is established, the diastolic vacuum is released and the networking channels of the folding sections and the porous sections disperse the vacuum and cause the tissue contacting portions of the diaphragm 74 to continue to be vacuumed onto the heart. Once in place, the cycles of diastole and systole (pumping) are initiated.

Total seal is not needed, unlike Anstadt's device, since significant holding forces can be utilised, even though there can be initially some leakage at the base. As serum, fibrin and tissue are gradually pulled into the porous sections by the vacuum , less vacuum leak occurs. Once attachment occurs at a particular location, the vacuum shifts further along the folds (toward the base) causing the next section to attach, and so forth.

Once good attachment is obtained, pumping through the driveport 47 is begun. The device 70 is held in place not only by the vacuum, but by the serum, fibrin and tissue which has been pulled into the interstices of the porosity. Unlike the Anstadt cup, sheering expulsion of the heart then becomes highly unlikely. Much less vacuum pressures and volumes are needed to allow pumping. After chest closure, suction can be maintained with a low pressure suction bulb. After a several days to a week, but less than two weeks, sufficient biointegration of tissue has occurred to secure the device 70 in place, without having to rely on vacuum for application of active diastole. This is a significant advantage, since momentary failure of the vacuum on the Anstadt device will result in irreversible expulsion of the cup from the heart. This has significant advantages for the patient, since unlike the Anstadt device, as already mentioned, and unlike currently available heart assist devices such as the Novacor and TCI Left Ventricular Assist Device complete removal of all pumping and vacuum systems is possible without serious consequences to the patient. (Even brief non-pumping of

the Novacor and TCI devices predisposes the pumping chambers and conduits to clotting, subsequent reactivation which can then cause thromboembolism and death.) With the device of the present invention, the pumping function and energy can be slowly, rapidly or instantly decreased to determine if the patient's own heart function can maintain the patient. In an emergency, the patient or a non-trained person can assist the heart muscle 14 by feeling the patient's pulse and activating a foot pump, or other such low tech device can be utilised to activate the cup diaphragm in time with the patient's own heart beat. This has significant advantages and can allow for emergency application of the device in an ER or other non-operating room arena as an emergency life saving measure. In this scenario a very small lightweight sterile pack, including the device 30 with its attached lengths of drive port 47 and temporary vacuum port 44 hooked to a vacuum bulb, with a hand or foot operated bellows to activate the device, could be on hand in ambulances, rural hospitals or third world settings; the device applied; manually pumped, while the patient is transferred to an appropriate center where the automatic pneumatic driver as described herein and more sophisticated care can be given.

Once in place, the continuous pressure of systole-diastole holds the biointegrating porous sections 71 in place. To prevent loss of contact between the epicardial surfaces and the biointegrating porous sections, initially no negative or only very low vacuum is used during the driving function (as opposed to the vacuum holding system)

to assist the natural heart filling. Thus, negative pressure or vacuum during diastole which grossly pulls the biointegrating sections away from the heart should be minimised initially since it can serve to impede biointegration altogether. Thus, even without the temporary vacuum port functioning, the positive pressure of systole will tend to expel any air, serum and/or blood which accumulates. Thus, the temporary vacuum port is only absolutely needed at surgical application.

On the other hand, the pressure of systole causes inward involution of the smooth folding sections and is the primary mechanism by which the decrease in surface area and volume occur. This is motion of the smooth folding sections 72 upon themselves and not on the heart surface to any significant degree. The relatively more rigid biointegrating porous sections 71 come together as they force the surface of the heart to contract (either totally assisted or partially assisted, or later after biointegration passively). This motion is created within the elastic matrix of the epicardium and heart muscle themselves, requiring no shearing at the biointegrating porous sections 71 tissue interface itself. This motion without gross shearing, allows the biointegrating porous sections 71 to biointegrate.

The systolic pressure, the vacuum of the holding system, and the resultant micromotion act together to speed and aid the biointegrating mechanisms as the heart is forced to contract. They act synergistically to pull amounts of blood and serum into the interstices of the

biointegrating porous sections 71 which act as a scaffold for the biointegration systems. In addition, any seroma or haematoma formation between the heart and the biointegrating porous sections 71 are gently massaged away and either into the biointegrating porous sections or away into the draining function of the both at the biointegrating porous sections and the smooth folding strips. In addition to these mechanisms, the continuous or intermittent vacuum application pulls adjacent vascularized tissue into the initial opening channels of the porous interstices of the biointegrating porous sections 71. By appropriate design of the widths, contours and orientations of the biointegrating porous sections 71 and the adjacent widths, contours and arientations of the smooth folding sections 72 a design allowing biointegration and long term pumping across the delicate epicardial surfaces can be accomplished.

The diaphragm member can be somewhat larger than the heart, the increased size accommodated by the folding smooth sections. Alternatively it can be slightly smaller, the size difference accommodated by the heart (not preferable), or partially accomplished by the elastic distension of the diaphragm member itself, primarily in the smooth folding sections and can be assisted with negative pressure at diastole.

Because of the porous matrix used on the inside of the cup 31, a circumferential sealing device may not be necessary. This can be implemented by connecting one suction line into each of the annular chambers 62, 63, 64,

65 such that each suction line is in communication with the porous matrix of the textured surface which will disperse the suction force as soon as suction resistance is met when the porous matrix is applied to the heart surface. Leakage of suction from that part of the porous matrix which is not applied to the heart surface is allowed since suction resistance is built up within the porous matrix as the suction disperses. This behaviour is aided by having the chest closed where the holding suction effect becomes more effective and can have an effect similar to a chest tube. In particular circumstances vacuum can be derived from chest tube lines.

The advantages of an implementation according to the third embodiment over previously disclosed devices include allowance for:

1. the excursions of the heart during diastole and systole, without significant sliding of the diaphragm material over the epicardial surface of the heart
2. the gradual decrease in heart size, from a failing heart to a non-failing heart status, by allowing the biointegrated sections to come more closely together,
3. the controlled removal (or partial removal) of the biointegrated parts of the membrane during device removal, by cutting along the non-biointegrated smooth folding section folds allowing for sequential strip dissection of the biointegrated sections,
4. the directed removal of fluid accumulations during and after biointegration, by the established network of

channels created within the smooth folding sections and other smooth sections

5. the specific and purposeful design to control and optimise diaphragm folding during the systole-diastole cycle, to thereby improve durability, longevity, and reliability of the membrane 35

6. Providing for and encouraging many small folds over a much larger surface area, rather than 3-5 folds which naturally occur in a uniform inner flexible diaphragm pumping a heart.

7. the ability to specifically lubricate the folds of the diaphragm folding sections, by introducing coatings or lubrications both *in vitro* during sac fabrication and *in vivo* while implanted along the folding networks.

8. the "better dispersion of pressure between the diaphragm and natural heart ventricles," discussed in the Anstadt patent at 3:67-68, here we create a better vacuum chamber which cannot be plugged at or by the apex of the heart; initially because of the multiple channels created by the dimension transitions at the porous-smooth section interfaces and within the open celled porous sections themselves (This provides vacuum outlets similar to vacuum bagging of large fibreglass parts, which secondarily reduces the size of the device and since it no longer needs the "inwardly extending elastic lip or rim 10" of Anstadt 3:59.

9. the use of an inflatable collar instead of "inwardly extending elastic lip or rim 10" at 3:59, in Anstadt

which may or may not have a biointegrating epicardial opposed surface.

10. the removal of all driving, vacuum or other assisting equipment without untoward results.

11. the re-initiation of pumping function after cessation of pumping without untoward results.

12. the emergency pumping by a low technology (muscle or foot powered) pumping device by non-trained personnel.

With reference to Fig. 10 there is shown a generalised fourth embodiment of the invention comprising a member 80 adapted to envelop at least the ventricular portions of a heart muscle (not shown) and further adapted for attachment to at least portions of the heart by means of biointegrating material 81 which is formed as part of or is, itself, attached to the inside surface of the member 80.

The cardiac assist device 79 of the fourth embodiment is adapted to apply a periodic generally inwardly directed force to ventricular portions of the heart thereby to assist systole of the heart.

The inwardly directed force can be applied by inducing a relative periodic shape change to member 80 by means not shown, but which can include, but is not limited to, the arrangements of previously described embodiments wherein the member 80 is constructed as a diaphragm member supported by and acting against a cup or like resilient externally mounted support device.

In this embodiment the biointegrating material 81 is formed in a cross hatch pattern as illustrated in the inset of Fig. 10 comprising longitudinal strips 82 intersected periodically by cross longitudinal biointegrating strips 83.

This arrangement leaves isolated sections 84 of smooth surface not adapted for biointegration. In this instance the isolated sections 84 are of generally rectilinear shape and are arranged to be less resilient than the biointegrating strips thereby allowing them to provide flexibility in the structure.

The biointegrating material 81 can be formed in accordance with the methods taught in US5,589,176, and US5,605,693, which patents are incorporated herein by cross-reference.

Alternatively, materials made by the Replamineform process can also be suitable.

What is necessary is that there is sufficient biointegration to cause adequate attachment of the member 80 to at least sufficient portions of the heart such that the membrane 80 can apply at least the necessary periodic generally inwardly directed force to ventricular portions of the heart thereby to assist systole of the heart without slippage occurring between the exterior heart surface and the interior membrane surface.

In situations where an outwardly directed force is induced in the member thereby to assist dyastole of the heart it is necessary that the attachment force is at least

as great as the outwardly directed force if detachment of the member from the heart is to be prevented.

Further Embodiments

In a fifth embodiment, a design of a corset cardiac assist device 200 is now shown in Figure 11 and Figure 12. In this instance the cardiac assist device 200 includes, as illustrated in Figure 11, an upper suturable band 115, an outer porous biointegratable surface 95, a drain fixation loop 125, an inner porous biointegratable surface 93, independent pneumatic chambers A-E, a lower sewing ring 122, drive lines S and V, an outer pneumatic chamber wall 94, and a removable suction drain 105.

With reference to Figure 12 the inside view additionally shoes drive lines S through to W, the upper sealed scalloped sections L through to P, the longitudinal sealed sections F through to J and F', cuff 130 for surrounding the exit site for drive line S and cuff 230 surrounding suction drain 105 and its exit site.

As shown in Figure 13 a cuff 140 can surround, collectively, drive lines S through to W and their collective exit site.

This embodiment shows the elegance of the adjustability of design for manufacturing, the adjustability at the operating table, and the built in redundancy and forgivability of the device 200.

Five independent pneumatic chambers A, B, C, D, & E as were described and shown in Figure 6 are fashioned running length wise this time, from the base 201 of the apex 202,

by sealing the inner pneumatic chamber wall or inner diaphragm member 93 to the outer pneumatic chamber wall or outer cup member 94 at the sealed longitudinal sealed sections F, G, H, I, J, F', running longitudinally, which are joined to base or upper sealed sections 100, and individually lettered in the figures as L, M, N, O, and P. and are also joined to the apical or lower sealed section 101 at the apex, as shown in Figures 11 and 12. The smooth folding sections previously described, are essentially fixed to the cup, to provide for the ultimate control and longevity of the folding sections. The sealed sections thus create independent pneumatic chambers (A, B, C, D, and E). In addition the upper sealed sections 100 can be fashioned so that the shape creates a section of a circle or an arc, thus creating a convex upper border to the independent pneumatic sections, shown as L, M, N, O, and P. This scalloped surface thus created has certain advantages. First, the pneumatic chamber thus created has less built in stress with this design. In addition, the scalloping greatly assists in placement of the base of the goblet or parabolic double open-ended cup at its superior or base opening to the atrial appendages without encroachment. By rotation of the device, the appendages of one or both auricles can be placed into the v-shaped through V where inflation of the pneumatic chamber causes the least dimensional change to these delicate appendages. Also, this allows more superior placement of the independent pneumatic chamber on the heart itself, making pumping more efficient. In addition, this relieved area without any

device or material, can be positioned to not encroach on the more major portions (proximal arterial system) of the coronary arteries.

As previously discussed in a described embodiment for the biointegrating strips of the goblet design (17-16), the greatest width of a pneumatic chamber, would be at the greatest equatorial diameter, tapering from this location to the base and the apex. Additional control of the shape of the independent pneumatic chambers can be accomplished by changing the width of the sealed sections F, G, H, I, J, F'. By having these sealed sections the widest at the equator and tapering toward the base and the apex, a relatively cylindrical shaped pneumatic chamber is created. By having the reverse for the sealed sections, a more rounded, balloon shaped independent pneumatic chamber is created, even with the same double taper for the uninflated pneumatic chamber widths. These 2 effects taken together can control the shape of the funnel device and vary it from being a relatively flat funnel shape or more of a goblet shape with double complex curves which follow the actual shape of the heart more closely.

The pneumatic chambers may or may not be the same dimension. Specific right to left pumping control can be accomplished by having different numbers and widths of independent pneumatic chambers opposing the right or the left ventricles. Multiple fit trials with and without pumping on live animals have been undertaken to document these principles. Because of the variability from animal to animal, and failed heart to recovering heart, there is a

spectrum of sizes that are applicable. This description will just be of one embodiment. In the five chambered illustrative design of Figures 11 and 12, there are three chambers placed opposite the right ventricle, and two opposite the left. For diagram purposes (and also for our animal prototyping and animal pump studies), the goblet shape has been reduced to a funnel comprised of flat sheets 93 and 94. The general funnel has a base circumference of 31cm and a longitudinal length of 13.5cm. In a more refined preferred embodiment, these flat sheets can be matching double compound curves more closely following the contours of the outside surface of the heart which when attached together at F and F' would recreate the goblet shape more closely resembling the heart. For simplicity, we will describe the three right-ventricle opposed and the two left-ventricle opposed pneumatic chambers and sealed sections as having the same dimensions and represented as flat sheets. It is realised that having the pneumatic chamber opposing the midportion of the myocardium composing each ventricle, that upon inflation more direct compression of the fluid within the ventricle will take place. Those chambers overlying the inter-ventricular septum will have less blood ejection (for the same pneumatic tube inflation) than if placed at the midportion of the ventricle.

By having the width dimensions smaller for the right ventricle, upon inflation of the pneumatic chamber, less expansion of the independent pneumatic chamber into the myocardium (and thus displacing the blood within the ventricle) occurs and therefore less pressure for the right

side. In figures 11 and 12, the three pneumatic chambers of the right ventricle have a width of 5cm at the diameter line of the start of the scalloped edge 100 as shown at L-P. The left ventricle opposed pneumatic chambers, here two, have a greater dimension measuring 8cm at the start of the scalloped edge shown at Y. These would be sealed separately from each other as sealed sections of 0.5cm, as would be the sealing width of the superior (base) and inferior (apex) sealed sections for this illustrative example. The length the pneumatic chambers is 13.5cm, but shorter and longer lengths have been used. The longer lengths have an advantage of accommodating failed hearts which have expanded not only in circumference but in length. By pulling the apex of the thin failed, stretched out heart into the longer apex device, better conformity and support occurs. This extra length is also accommodated by the adjustment in the circumference to be described later. In this way, excess length can be brought past the end of the apex of the heart, and still not impinge on the atria, allowing more forgiveness in sizing and placement. The width of the tapered pneumatic chambers (doubly tapered in the goblet design) for the left un-inflated pneumatic chambers at the bottom portion or apex end of the device is 4cm and for the right is -2.5cm. It is also anticipated that the taper ratio of these left and right chambers, here 2:1 need not be the same. If differing taper ratios are used, the pneumatic chamber orientation successively creates an axis for the pneumatic chamber which is not exactly oriented to the longitudinal axis. Some of this

skewing may help in placing the sealed sections, which do not inflate against the myocardium, following the course of the more obliquely placed descending coronary vessels.

These independent pneumatic chambers are provided with and attached to independent drivelines Q, R, S, T and U, one longer section shown here (S) at the apex of pneumatic chamber C, to provide for independent control of each pneumatic chamber. It can be seen in this embodiment that the taper of the pneumatic chamber terminates into the driveline attachment at the sealed inferior sections, on each side of the driveline.

This redundancy and independence of the pneumatic chambers to the outside must not be underestimated. This design may not have been considered in the past because of percutaneous exit site considerations. Utilising biocompatible and biointegrable materials of the type disclosed in US 5,605,693 we have been able to show consistently in animals and humans that the creation of a stable percutaneous exit site over long periods of time is possible. Access to the outside eliminates the extreme complexity of the design of other devices and which is to say, transcutaneous energy systems are not needed, implantable energy converters are not needed and compliance chambers are not needed.

In this preferred embodiment, shown in Figure 13, the five exiting drivelines could be brought out through the skin as five independent exit sites, but more preferably they are joined together without dead spaces or pockets with biocoompatible and biointergratable coaxial sheath

cuffs coverings 140 just after leaving the pneumatic chambers, and exit through a single exit site as a single coaxial tube with five independent internal vent tubes, then again becoming independent for attachment to individual or common drivers. Other vent tube attachments have been tried, but with this configuration, inflation of the pneumatic chamber starts at the apex of the heart and progresses toward the valves, which stimulates blood ejection in a normal heart. This configuration also allows a handle, of sorts, to hold the device, either formed into the cup or before closing the device closure strips to be discussed later, which has been found helpful at surgery and also assists prevention of touching either inner or outer biointegratable surfaces of the corset itself. This design also prevents kinking of the pneumatic chamber-vent tube attachment junction and fits better into the chest and allows better routing to the exit site. It also allows the least restrictive entrance and exit for the device pumping medium, especially if they are chosen to be liquids, rather than gasses. Appropriate tapering transitions between the vent tube and the pneumatic chamber can be accomplished, especially by varying the configuration and dimensions of the sealed strips in this location. The smaller right sided pumping pneumatic chambers will have a smaller diameter vent tube, whereas the larger left-sided chambers will have larger vent tubes as shown in Figure 13.

This controllability and redundancy is valuable for many reasons.

Besides the mechanisms of right to left control described above, separate parameters of pressure, volume of inflation, dP/dT, onset of chamber pumping relative to the EKG, etc. can be accomplished with the exteriorised system.

If a failure of one of the pneumatic chambers occurs, continuation of the assist provided by the remaining pneumatic chambers is maintained. Rather than the entire device failing, possibly with catastrophic results and death, isolation of the failed device (by a driver detection system) can quickly take this failed chamber off line. This can be accomplished without the necessity of stopping the cardiac assist provided by the other pneumatic sections.

In this embodiment we do not provide a totally implantable device. It will require an efficient portable driver designed to deliver the most assist for the least energy. Tuning of the device after implantation and recovery can be accomplished by testing each independent pneumatic chamber to see which one or which combination provides the patient with the most cardiac assist measured either by cardiac output or coronary blood flow, for the least energy expenditure of the corset assist device. This can permit one or more of the chambers to go on passive-pumping mode and to be vented into the driving medium without actually being actively pumped. Not only is this an advantage for portable drivers in conserving and maximising the energy expenditure, it provides redundancy of pneumatic (or hydraulic) chambers so that for very long implantations where the flex life of the actuated pneumatic

chambers is exhausted, pumping can be switched to these non-pumped, non-flexed, non-stressed pneumatic chambers, for back-up.

In addition, the pneumatic chamber operating profile pattern and optimal parameters for cardiac assist may change with the progress of a recovering heart. These parameters may then be easily changed during the course of the disease process, either in cardiac recovery or decline.

The exteriorised system would be an advantage to be able to change the driving fluid medium if contamination from imbibed body fluids such as sodium chloride, water, lower molecular weight components of serum or other trans-polymer body fluids occur through the pneumatic chamber polymer, (in this case sheets 93 and 94). Truly hermetically sealed flexible polymers within the body are difficult to achieve due to the semi-permeable nature of almost all flexible polymers.

Porous, bio-integratable surfaces of the types previously described can be applied to the entire surfaces 93 and 94, or in predetermined patterns as described in earlier embodiments with smooth and porous sections. There are certain benefits to each. In the fifth embodiment, a porous biointegratable surface can be used and applied to all of the surfaces of the permanent part of the cardiac assist device 200, but with different thicknesses and pore size differences. One thickness of this material can be used, but it has been found optimal in other studies that varying the thickness and the pore size of the porous biointegratable surface for certain applications has

definite benefits. The optimum thickness for this corset cardiac assist device 200 of the fifth embodiment at the center of the pneumatic chambers is 1.25mm plus or minus 0.50mm but with the thickness decreasing toward the sealed sections, where it is 0.75mm plus or minus 0.25mm. This differential thickness for the biointegratable surface allows maximum vascularity, biointegratable tissue and elastic modulus match at the point of maximal excursion and pressure of the pneumatic chamber. It will also allow for some thickness allowance for positioning of the drains to be discussed. The independent drivelines, or the coaxial drivelines already discussed, can also be surfaced with this material.

In this fifth embodiment, to create a corset from a cup or goblet design, the cup is opened by dividing longitudinally, the longitudinal sealed section F, into two parts F and F' thereby opening the cup into a corset. Attached to F and F' are device closure strips which are non-pneumatic overlapping sections, shown in Figures 11 and 12 as 106 and 107, here made from an appropriate biocompatible material such as Dacron polyester velour G and G', whereby the corset can be fashioned back into a parabolic doubly open-ended cup by suturing the two strips together longitudinally. In an alternative embodiment, the strips G and G' can be made from Velcro, and the establishment of the parabolic doubly open-ended cup made by securing the opposing Velcro strips together. Alternately, hook eyes can be used with the hooks placed along strip G on one side and the eyes along strip G' such

that when the hooks and eyes are fastened together, a parabolic doubly open-ended cup is established. Other appropriate securing systems are possible. In each of these strip variations, the size of the circumference of the cup can be controlled and adjusted at surgery. In the case of the Dacron polyester velour example, the surgeon can sew the two opposing strips together at the appropriate locations, cutting and trimming for butt-end apposition or overlapping as desired. Similar control by the surgeon at implant would be accomplished in the Velcro and the hook-eye examples. By having these strips of the appropriate width, in the preferred embodiment 4 centimetres each, large variations in sizing can be accomplished with a single device at the operating table without the necessity of multiple sized devices. In addition, it is anticipated that in some cases, the surgeon may wish to not fully close the corset, but suture the strips directly to the heart, thereby selectively not applying pneumatic chambers to, or over a portion of the heart.

It is further anticipated that since the pneumatic chambers are independent and separate, in some circumstances the surgeon may wish to remove one or more independent pneumatic chambers to reduce the overall circumference of the device. In this example this would be performed by cutting along sealed section J and removing independent pneumatic chambers E. In this circumstances the sewing strip 107 would be removed from the removed independent pneumatic chamber E and re-sutured to the longitudinal sealed section J or to part of the independent

pneumatic chambers walls 93 and 94 if the section is made through them rather than through J.

Drains

As described previously, the preferred embodiments of Figures 11 and 12 have multiple drains or low vacuum suction apparati provided to each pneumatic chamber on the sac or myocardium or heart contacting surface. One design of the removable drain is shown at 105 and one design is shown at 110. As discussed previously, these provide for the removal of blood and fluids from between the myocardial surface and the opposed biointegratable surfaces of 95. This is important both for enabling the biointegration of the myocardial tissues into the biointegratable surface without interposed body fluids of blood and serum or transient substances such as haematoma and fibrin clots, which can be removed by these drains before, as, or after they form. In addition, the low level suction also is dispersed within the pores and interstices of the biointegratable surface 95 and creates an effect similar to many mini-suction cups, pulling the adjacent tissues into the interstices and thus holding the corset (or cup or goblet) in place. This is accomplished with much lower vacuum pressures than are required with the smooth surfaced sac of Anstadt. This vacuum effect magnifies the coefficient of friction forces which develop between tissue and the porous surfaces present without the vacuum present. In fact, porous surfaced corset and cup devices without suction have been shown to stay in place during paced

assisted cardiac assist pumping with no vacuum assist of any kind.

Removable drain 105 is shown as a straight device with 5 drain holes along its course on sealed strip G but not extending past it. It is anticipated that newer drain designs with channels instead of holes can advantageously be substituted. An alternative design of drain 110 is shown with a bifurcated end providing suction and drainage to two adjacent pneumatic chambers C and D. These drains are provided with a cuff of biointegratable, biocompatible material shown as 130 to be placed at the skin exit site, thereby to prevent the colonisation of bacteria and biofilm along the course of the drain, and allowing removal with quick healing of the exit site drain channel.

These drains are kept in for variable periods of up to two or three weeks, as in the case with other surgical drains. They are then removed by pulling them out, as with other surgical drains. Their removal without dislodging the biointegrated tissues of 95 is controlled with drain fixation loops shown at 120 and 125 positioned over longitudinal strip G. These loops cause the drains to be removed in pure tension without disrupting the biointegratable tissues on either side of the drain during their extraction.

It has sometimes been found helpful for security during experiments to suture portions of the apex or the base to the myocardium at strategic locations. The upper scalloped edge is provided with a suturable bands of material shown as upper suturable band 115 and lower apex

sections between the pneumatic chamber-vent tube attachments are provided with suturable tabs of material such as Dacron velour previously mentioned shown as lower suturable tabs 116. By placing a few sutures into the myocardium as fixation sutures, movement of the device upon the myocardium is greatly reduced and the fine placement at the upper base just to the atrial appendages and atria is enhanced. Those tabs and strips which are not needed may be cut off or left in place depending on the circumstance.

The above describes only some embodiments of the present invention and modifications, obvious to those skilled in the art, can be made thereto without departing from the scope and spirit of the present invention.

Industrial Applicability

The method of attachment described can be applied to cardiac assist devices for the purpose of holding the devices in place on the heart, thereby to assist mechanically the beating of a heart.

CLAIMS

1. A cardiac assist device including

(a) a cup or like device adapted to receive at least ventricular portions of a heart muscle therein

(b) within said cup, a diaphragm member including a cardiac tissue contacting surface having a biointegrating membrane or layer by which at least portions of said diaphragm member become biointegrated with said cardiac tissue.

(c) a pneumatic chamber defined between at least a portion of said cup and a portion of said diaphragm member whereby relative positive and negative pressures can be alternately induced in said pneumatic chamber so as to cause, respectively, compression and distension of at least portions of said heart muscle so as to at least assist systole and diastole of said heart muscle.

2. The device of Claim 1 wherein said biointegrating membrane or layer comprises a plurality of strips of biointegrating material attached to or forming part of said diaphragm member and separated by portions of said diaphragm member having no biointegrating material.

3. The device of Claim 2 wherein said diaphragm member is caused to be attached to said cardiac tissue in a manner such that involution occurs during systole of said portions of said diaphragm member having no biointegrating material.

4. The device of Claim 1 wherein said cup is of substantially ellipsoid shape in cross section.

5. The device of Claim 1 wherein said biointegrating membrane or layer is applied in a pattern to said diaphragm member that allows

i. drainage of initial serous fluid to a temporary port

ii. passage of the coronary vessels without compression and

iii. controlled folding of the diaphragm member during inflation.

6. The device of Claim 1 wherein said biointegrating membrane or layer is arranged so as to develop vascularity thereby to improve infection resistance.

7. The device of Claim 1 wherein said diaphragm member varies in thickness and conformation so as to enhance sequential compression of the right ventricle and left ventricle.

8. The device of Claim 1 wherein initial attachment of said diaphragm member to said heart muscle is assisted by use of a tissue glue.

9. The device of Claim 1 wherein the continuous cyclic pressure of systole-diastole assists in biointegration of the cardiac tissue contacting porous surfaces of said biointegrating membrane.

10. The device of Claim 1 which is installed according to the following steps:

a. Initially no negative vacuum is used to assist the natural heart filling.

b. Further pressure of systole then inwardly involutes the smooth folding strips, causing the relatively more rigid biointegrating porous sections to come together, but also forcing the heart to contract, both at the biointegrating porous sections and the smooth folding strips.

11. The device of Claim 2 wherein said strips of biointegrating material are aligned in annular fashion about said diaphragm member.

12. The device of Claim 2 wherein said strips of biointegrating material are aligned in longitudinal fashion about said diaphragm member.

13. The device of any previous claim wherein said diaphragm member is treated with a lubricating substance in order to assist movement of those portions of said diaphragm member not having biointegrating material thereon relative to said heart muscle.

14. The device of Claim 13 wherein a tube communicates from said heart muscle to exterior said cup and acts as a conduit for vacuum and for fluid draining.

15. The device of any previous claim wherein said diaphragm member includes more than one layer with a lubricant disposed between adjacent layers.

16. The device of any previous claim wherein relatively more rigid biointegrating porous sections come together as they force the surface of the heart to contract (either totally assisted or partially assisted) whereby motion is created within the elastic matrix of the epicardium and heart muscle themselves, requiring no shearing at the

biointegrating porous sections-tissue interface itself thereby to assist biointegration.

17. The system of any previous claim wherein systolic pressure and the vacuum of the holding system and resultant relative micromotion between the heart and the porous material act together to speed and aid biointegrating mechanisms as the heart is forced to contract and act to pull amounts of blood and serum into the interstices of the biointegrating porous sections which act as a scaffold biointegration.

18. The system of Claim 17 wherein seroma or haematoma formation between the heart and the biointegrating porous sections are gently massaged away and either into the biointegrating porous sections or away into the draining function of both at the biointegrating porous sections and the smooth folding strips.

19. A method of attachment of a cardiac assist device to the heart; said cardiac assist device of the type including a member adapted for relative periodic shape change so as to apply a periodic generally inwardly directed force to ventricular portions of a heart thereby to assist systole of said heart;

said method comprising:

attaching a biointegrating membrane to at least a portion of said member which is in contact with an exterior surface of said heart;

causing said biointegrating membrane to attach to said exterior surface of said heart whereby said member becomes attached to said heart.

20. The method of Claim 19 wherein said member is further adapted to apply a periodic generally outwardly directed force to said ventricular portions of said heart thereby to assist dyastole of said heart.

21. The method of Claim 19 or Claim 20 wherein said member is a diaphragm member located within and adapted to act against a cup or like resilient support structure.

22. The method of any one of Claims 19, 20 or 21 wherein said biointegrating membrane is in the form of strips of biointegrating material separated by zones of non-biointegrating material.

23. The method of Claim 22 wherein the said strips are applied radially to said heart.

24. The method of Claim 22 wherein said strips are applied longitudinally to said heart.

25. The method of any one of Claims 22, 23 or 24 wherein said zones of non-biointegrating material are smooth and flexible so as to allow relative movement of said strips during use.

26. The method of Claim 22 wherein said strips are applied both radially and longitudinally to said member so as to define a plurality of isolated zones of non-biointegrating material.

27. The method of any one of Claims 19-26 wherein said biointegrating membrane is made by the Replamineform process.

28. The method of any one of Claims 19 to 26 wherein said biointegrating membrane is made by the process of utilising at least one removable open-cell porous mould form

comprising particles formed and shaped into a solidified mass of continuously interconnected particles defining continuously interconnected pores and connecting interstices.

29. A cardiac assist device for attachment to a heart in accordance with the method of any one of Claims 19 to 28.

AMENDED CLAIMS

[received by the International Bureau on 19 October 1998 (19.10.98);
original claims 4-10, 17 and 18 amended; remaining claims unchanged
(6 pages)]

1. A cardiac assist device including

(a) a cup or like device adapted to receive at least ventricular portions of a heart muscle therein

(b) within said cup, a diaphragm member including a cardiac tissue contacting surface having a biointegrating membrane or layer by which at least portions of said diaphragm member become biointegrated with said cardiac tissue.

(c) a pneumatic chamber defined between at least a portion of said cup and a portion of said diaphragm member whereby relative positive and negative pressures can be alternately induced in said pneumatic chamber so as to cause, respectively, compression and distension of at least portions of said heart muscle so as to at least assist systole and diastole of said heart muscle.

2. The device of Claim 1 wherein said biointegrating membrane or layer comprises a plurality of strips of biointegrating material attached to or forming part of said diaphragm member and separated by portions of said diaphragm member having no biointegrating material.

3. The device of Claim 2 wherein said diaphragm member is caused to be attached to said cardiac tissue in a manner such that involution occurs during systole of said portions of said diaphragm member having no biointegrating material.

4. The device of any one of Claims 1, 2 or 3 wherein said cup is of substantially ellipsoid shape in cross section.

5. The device of any one of Claims 1 to 4 wherein said biointegrating membrane or layer is applied in a pattern to said diaphragm member that allows

i. drainage of initial serous fluid to a temporary port

ii. passage of the coronary vessels without compression and

iii. controlled folding of the diaphragm member during inflation.

6. The device of any one of Claims 1 to 5 wherein said biointegrating membrane or layer is arranged so as to develop vascularity thereby to improve infection resistance.

7. The device of any one of Claims 1 to 6 wherein said diaphragm member varies in thickness and conformation so as to enhance sequential compression of the right ventricle and left ventricle.

8. The device of any one of Claims 1 to 7 wherein initial attachment of said diaphragm member to said heart muscle is assisted by use of a tissue glue.

9. The device of any one of Claims 1 to 8 wherein the continuous cyclic pressure of systole-diastole assists in biointegration of the cardiac tissue contacting porous surfaces of said biointegrating membrane.

10. The device of any one of Claims 1 to 9 which is installed according to the following steps:

a. Initially no negative vacuum is used to assist the natural heart filling.

b. Further pressure of systole then inwardly involutes the smooth folding strips, causing the relatively more rigid biointegrating porous sections to come together, but also forcing the heart to contract, both at the biointegrating porous sections and the smooth folding strips.

11. The device of Claim 2 wherein said strips of biointegrating material are aligned in annular fashion about said diaphragm member.

12. The device of Claim 2 wherein said strips of biointegrating material are aligned in longitudinal fashion about said diaphragm member.

13. The device of any previous claim wherein said diaphragm member is treated with a lubricating substance in order to assist movement of those portions of said diaphragm member not having biointegrating material thereon relative to said heart muscle.

14. The device of Claim 13 wherein a tube communicates from said heart muscle to exterior said cup and acts as a conduit for vacuum and for fluid draining.

15. The device of any previous claim wherein said diaphragm member includes more than one layer with a lubricant disposed between adjacent layers.

16. The device of any previous claim wherein relatively more rigid biointegrating porous sections come together as they force the surface of the heart to contract (either totally assisted or partially assisted) whereby motion is

created within the elastic matrix of the epicardium and heart muscle themselves, requiring no shearing at the biointegrating porous sections-tissue interface itself thereby to assist biointegration.

17. The device of any previous claim wherein systolic pressure and the vacuum of the holding system and resultant relative micromotion between the heart and the porous material act together to speed and aid biointegrating mechanisms as the heart is forced to contract and act to pull amounts of blood and serum into the interstices of the biointegrating porous sections which act as a scaffold biointegration.

18. The device of Claim 17 wherein seroma or haematoma formation between the heart and the biointegrating porous sections are gently massaged away and either into the biointegrating porous sections or away into the draining function of both at the biointegrating porous sections and the smooth folding strips.

19. A method of attachment of a cardiac assist device to the heart; said cardiac assist device of the type including a member adapted for relative periodic shape change so as to apply a periodic generally inwardly directed force to ventricular portions of a heart thereby to assist systole of said heart;

said method comprising:

attaching a biointegrating membrane to at least a portion of said member which is in contact with an exterior surface of said heart;

causing said biointegrating membrane to attach to said exterior surface of said heart whereby said member becomes attached to said heart.

20. The method of Claim 19 wherein said member is further adapted to apply a periodic generally outwardly directed force to said ventricular portions of said heart thereby to assist dyastole of said heart.

21. The method of Claim 19 or Claim 20 wherein said member is a diaphragm member located within and adapted to act against a cup or like resilient support structure.

22. The method of any one of Claims 19, 20 or 21 wherein said biointegrating membrane is in the form of strips of biointegrating material separated by zones of non-biointegrating material.

23. The method of Claim 22 wherein the said strips are applied radially to said heart.

24. The method of Claim 22 wherein said strips are applied longitudinally to said heart.

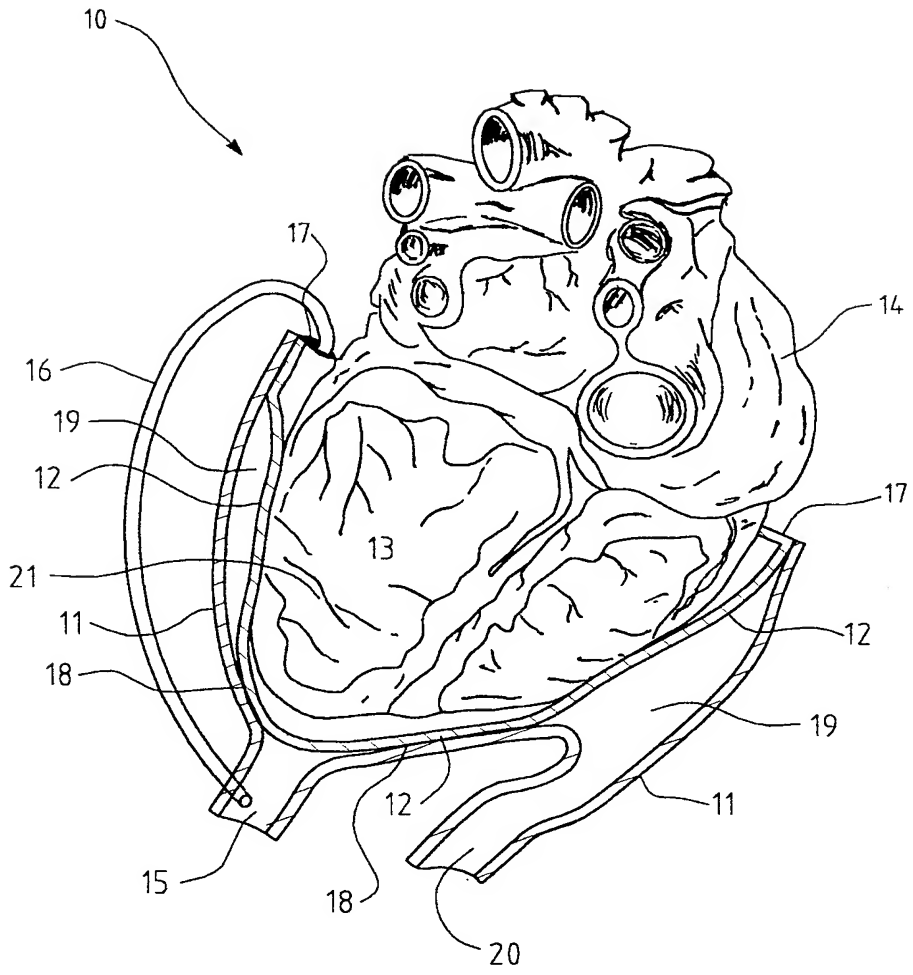
25. The method of any one of Claims 22, 23 or 24 wherein said zones of non-biointegrating material are smooth and flexible so as to allow relative movement of said strips during use.

26. The method of Claim 22 wherein said strips are applied both radially and longitudinally to said member so as to define a plurality of isolated zones of non-biointegrating material.

27. The method of any one of Claims 19-26 wherein said biointegrating membrane is made by the Replamineform process.

28. The method of any one of Claims 19 to 26 wherein said biointegrating membrane is made by the process of utilising at least one removable open-cell porous mould form comprising particles formed and shaped into a solidified mass of continuously interconnected particles defining continuously interconnected pores and connecting interstices.

29. A cardiac assist device for attachment to a heart in accordance with the method of any one of Claims 19 to 28.



Prior Art

Fig. 1

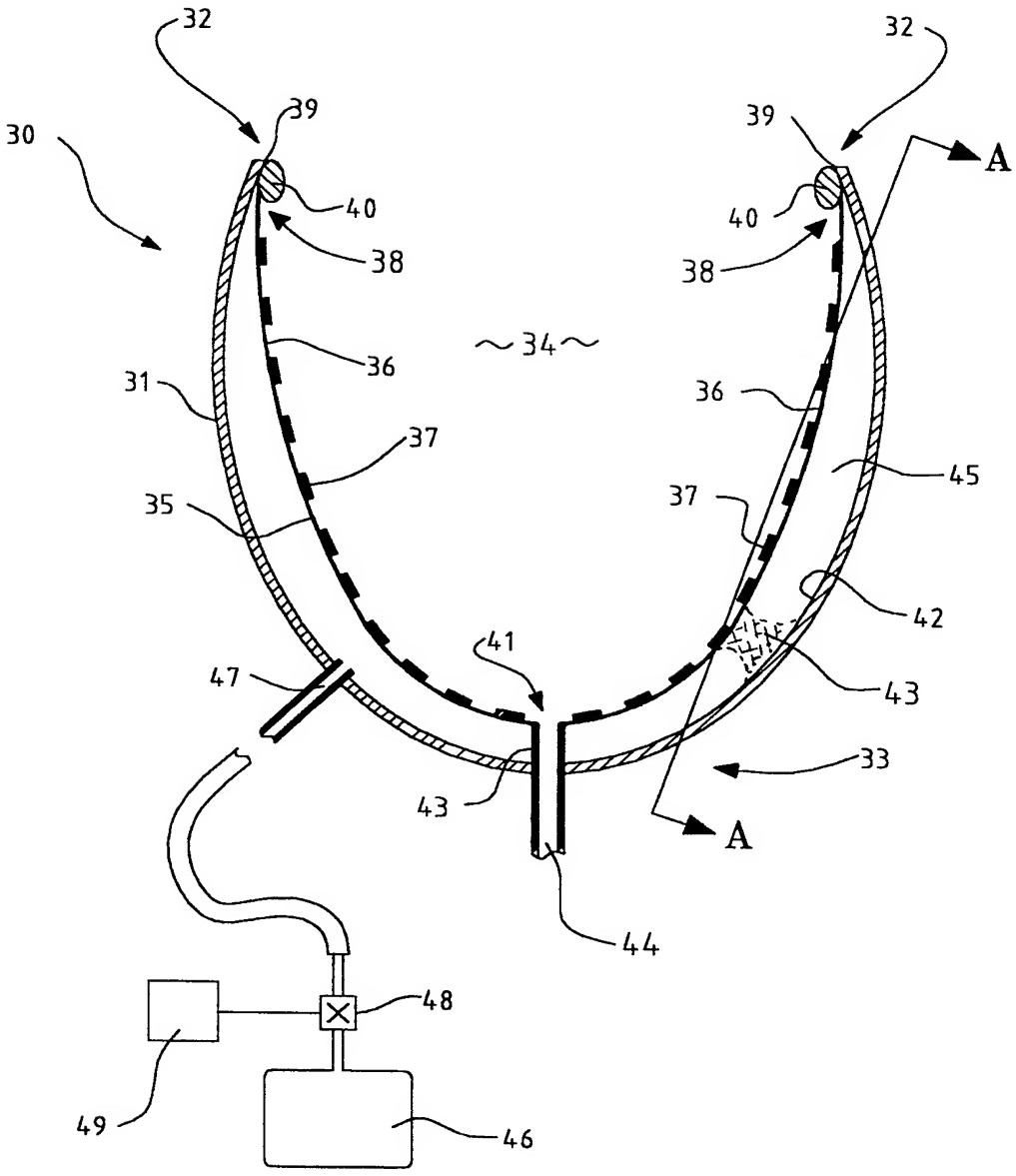

32
39
30
40
38
36
31
37
35
47
41
43
44
48
49
46
34
32
39
40
38
36
37
45
42
43
33
A
A

Fig. 2

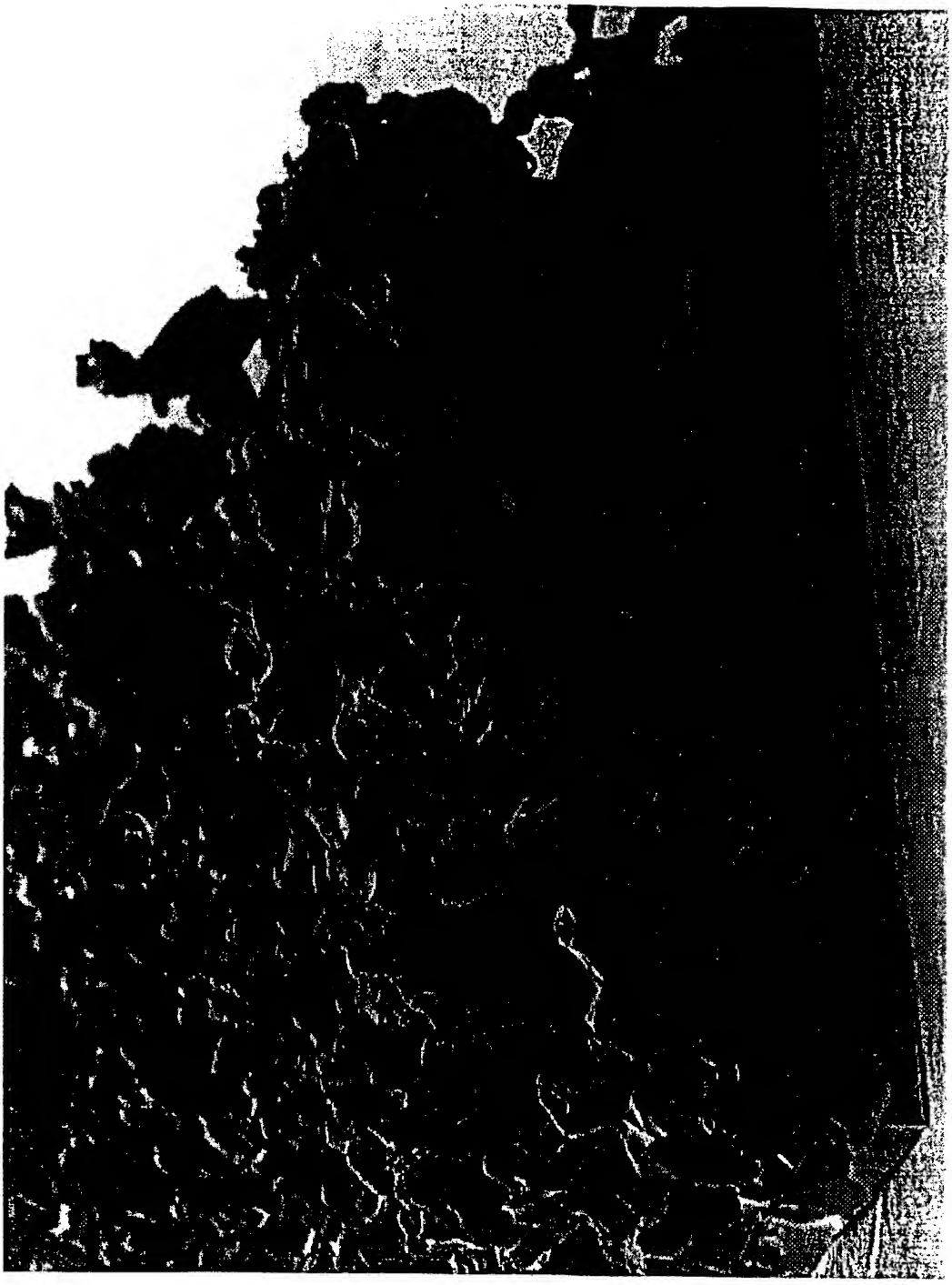
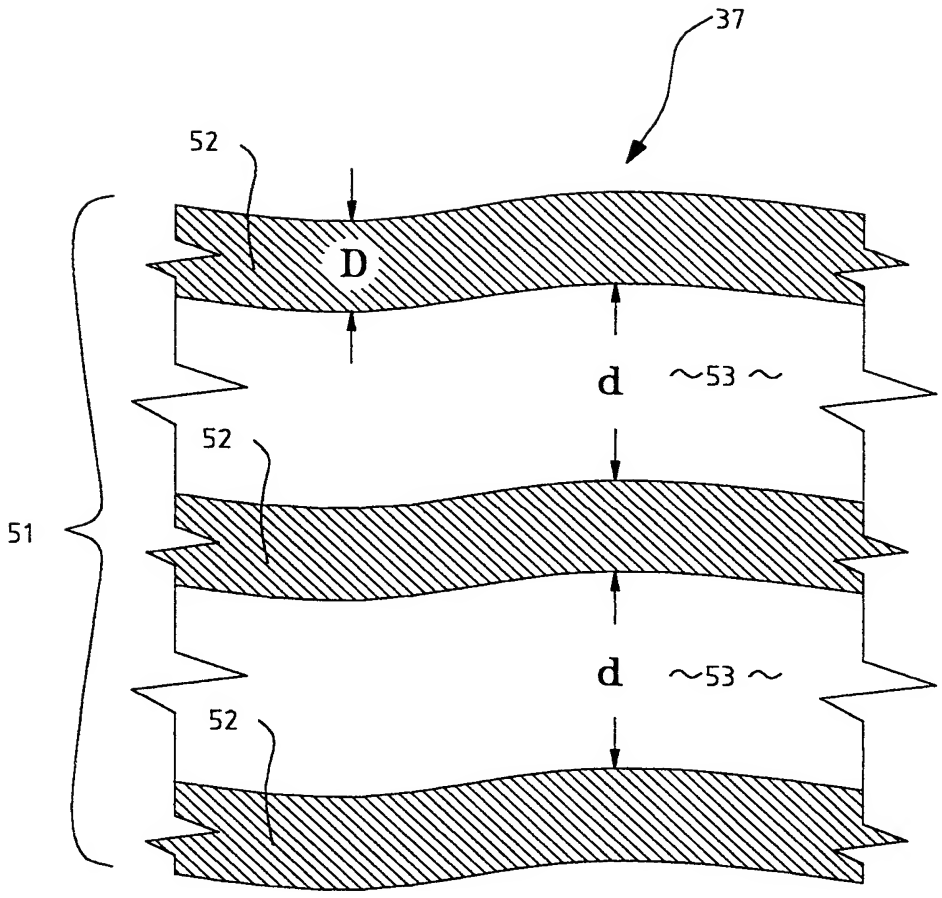


Fig 3



A–A

Fig. 4

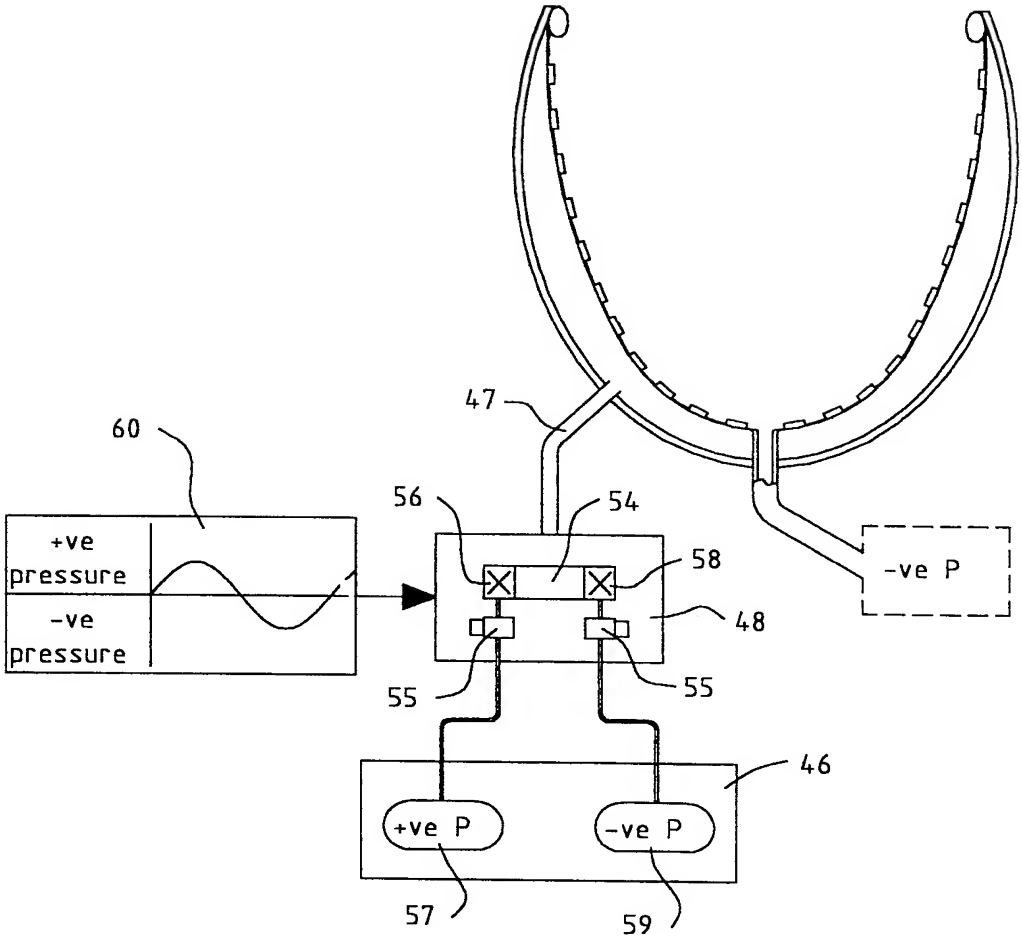
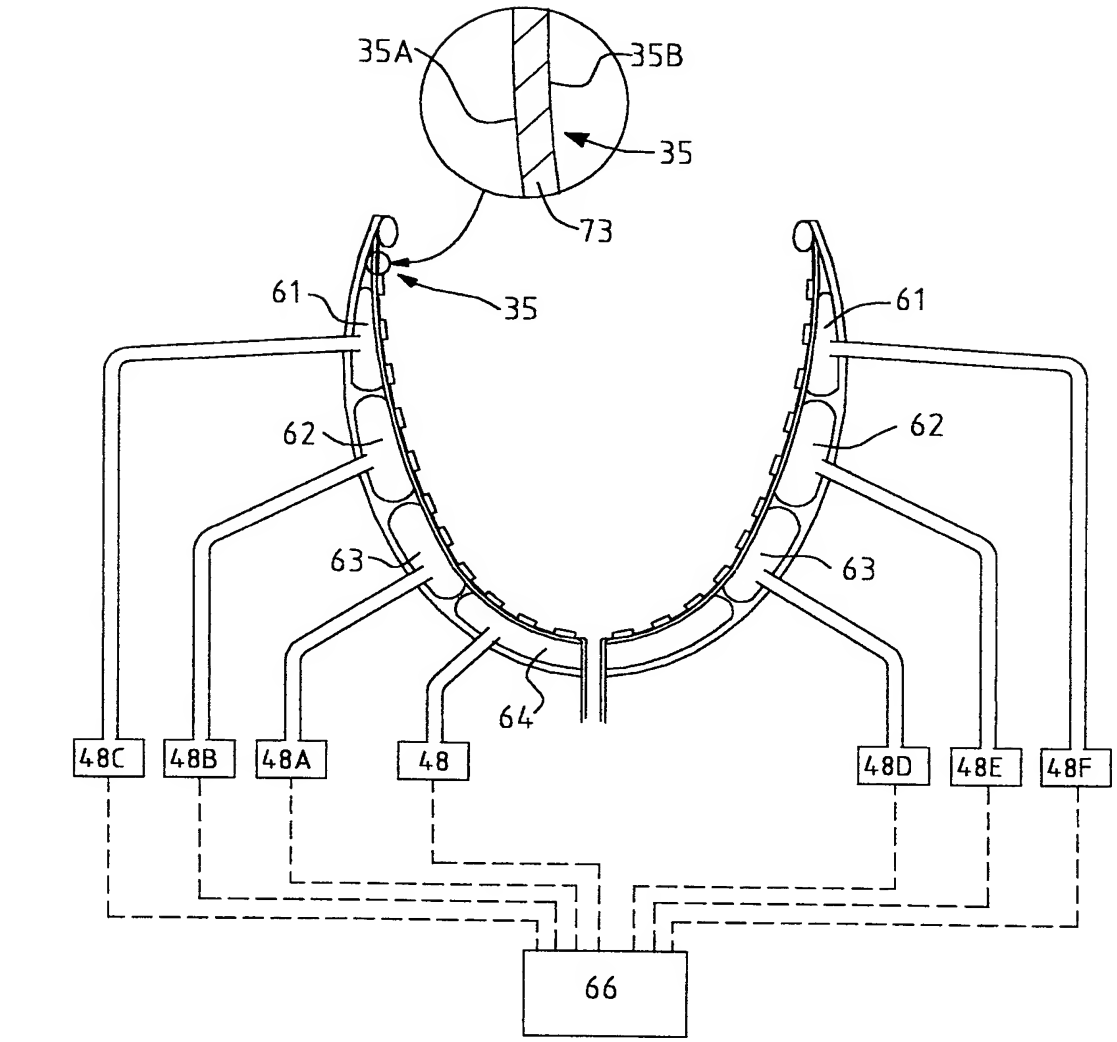
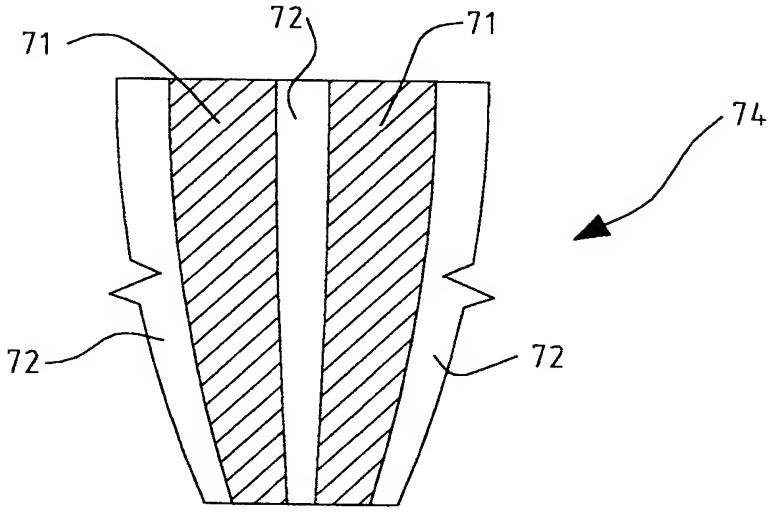

60
+ve
pressure
-ve
pressure
47
56
54
58
48
-ve P
55
55
46
+ve P
-ve P
57
59

Fig. 5


35A
35B
35
73
61
35
61
62
62
63
63
64
48C
48B
48A
48
48D
48E
48F
66


48A driver
+ve
-ve
48B driver
+ve
-ve
48C driver
+ve
-ve
48D driver
+ve
-ve
48E driver
+ve
-ve
48F driver
+ve
-ve

Fig. 6



Sec. BB

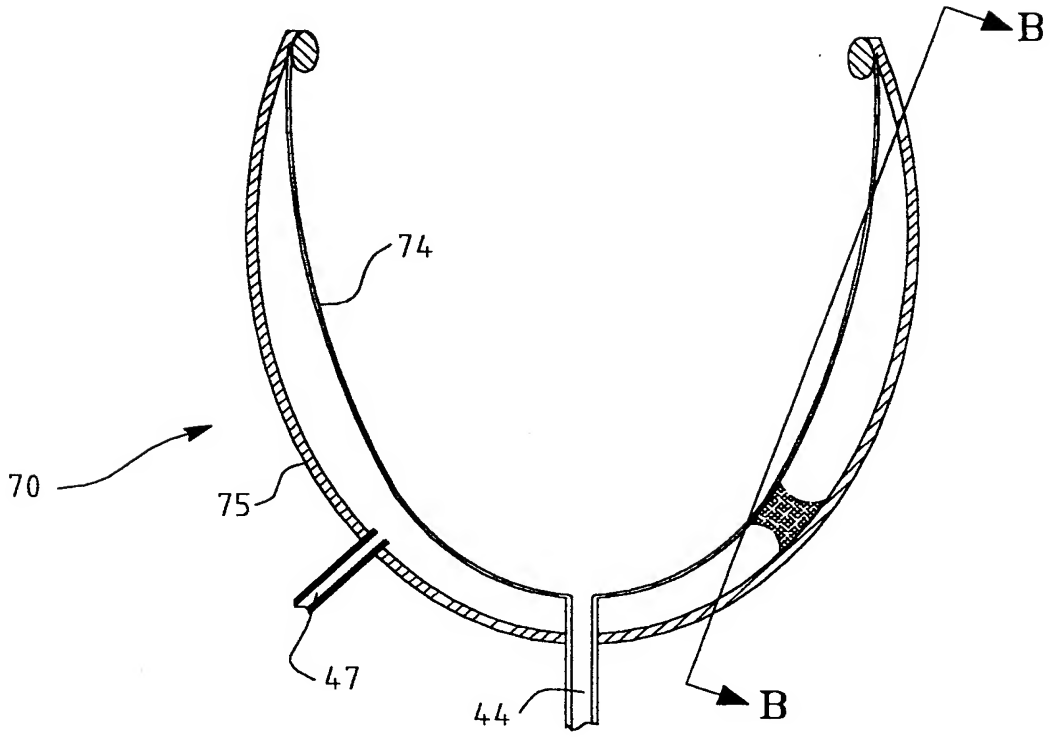
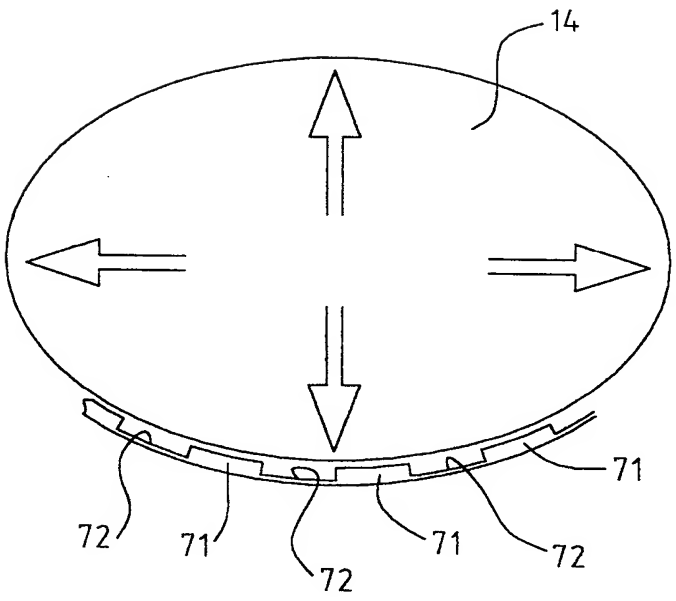
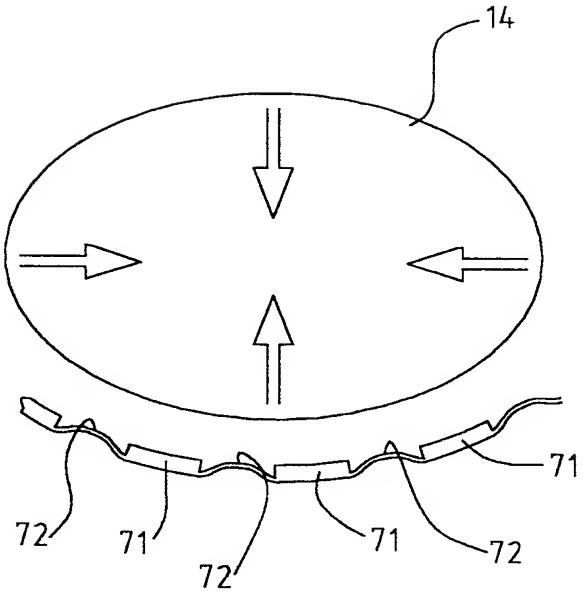


Fig. 7



DIASTOLE

Fig. 8



SYSTOLE

Fig. 9

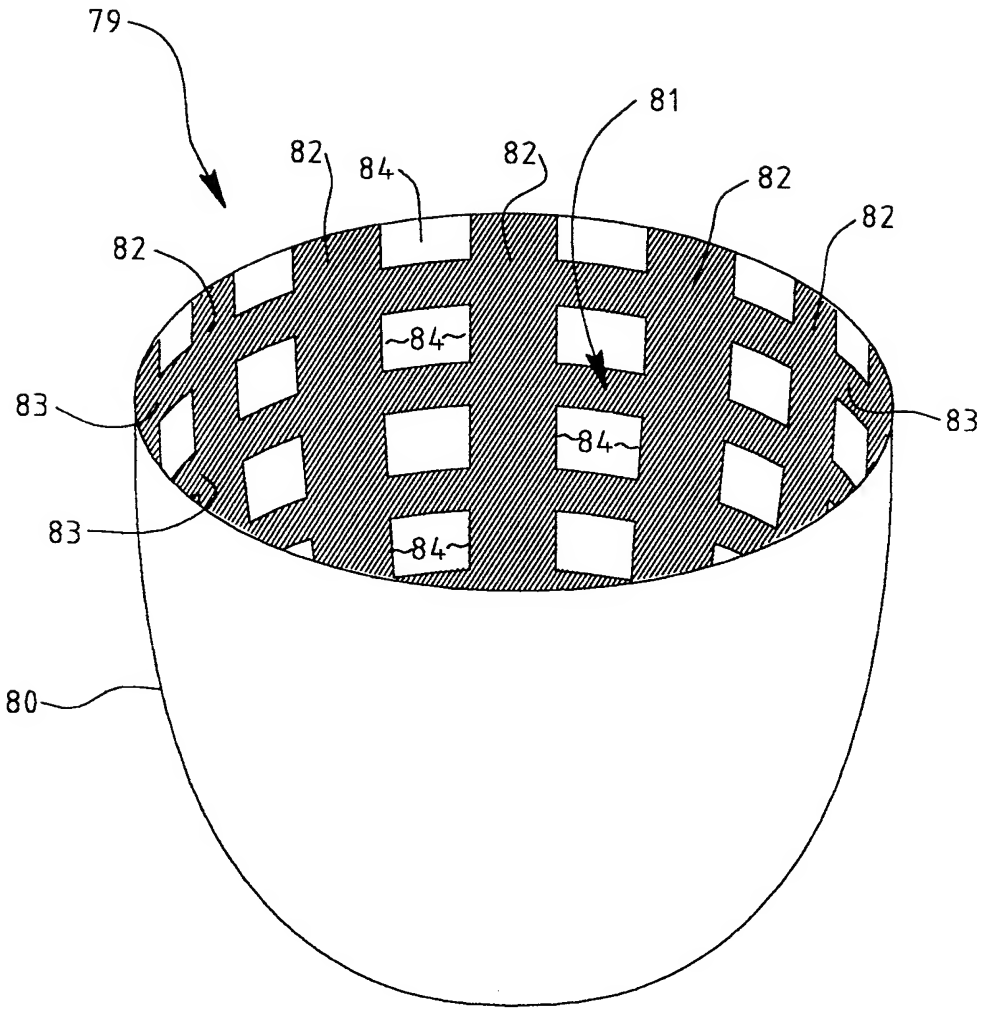


Fig. 10

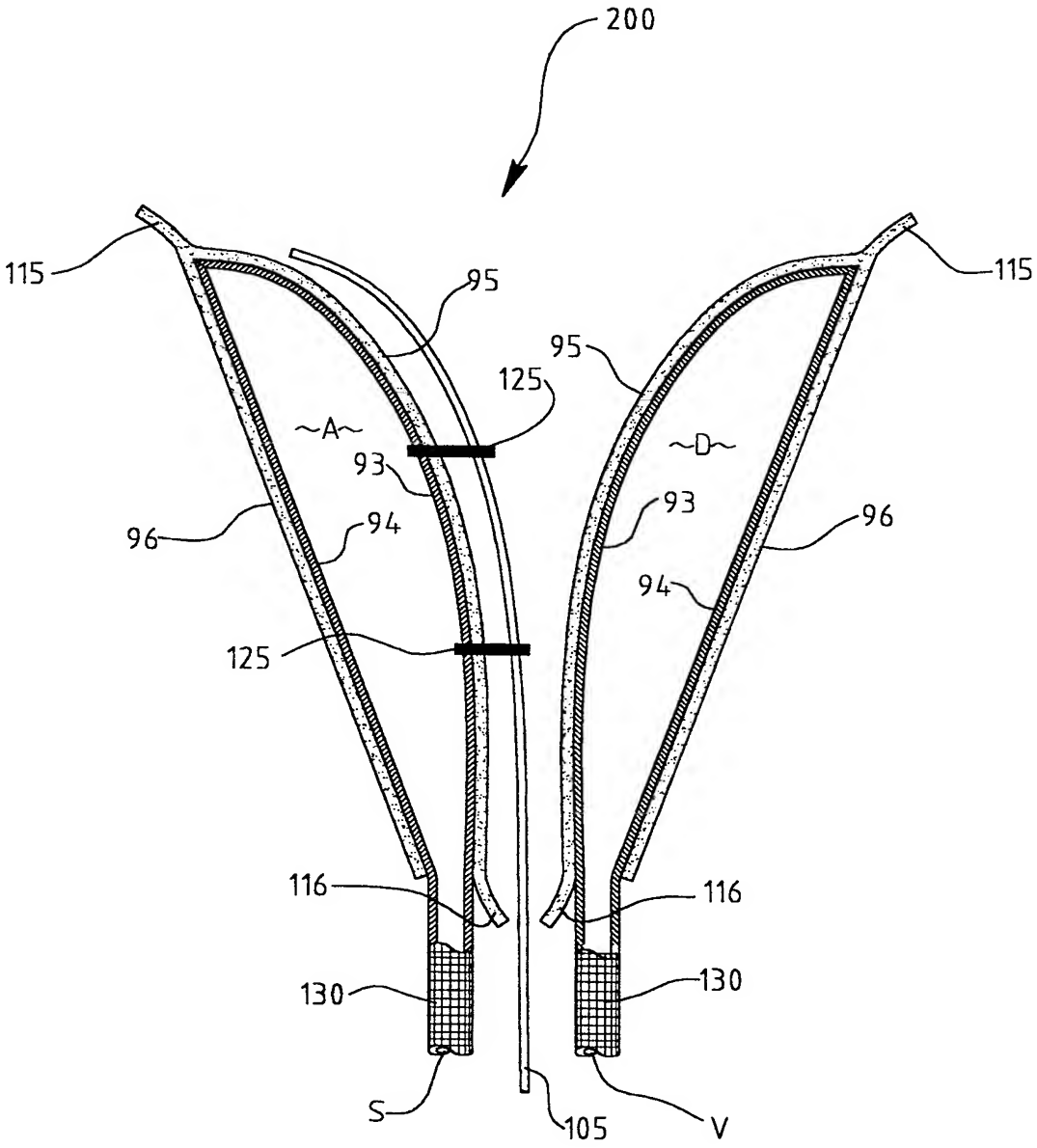

200
115
95
125
~A~
93
96
94
125
116
130
S
105
95
~D~
93
96
94
115
116
130
V

Fig. 11

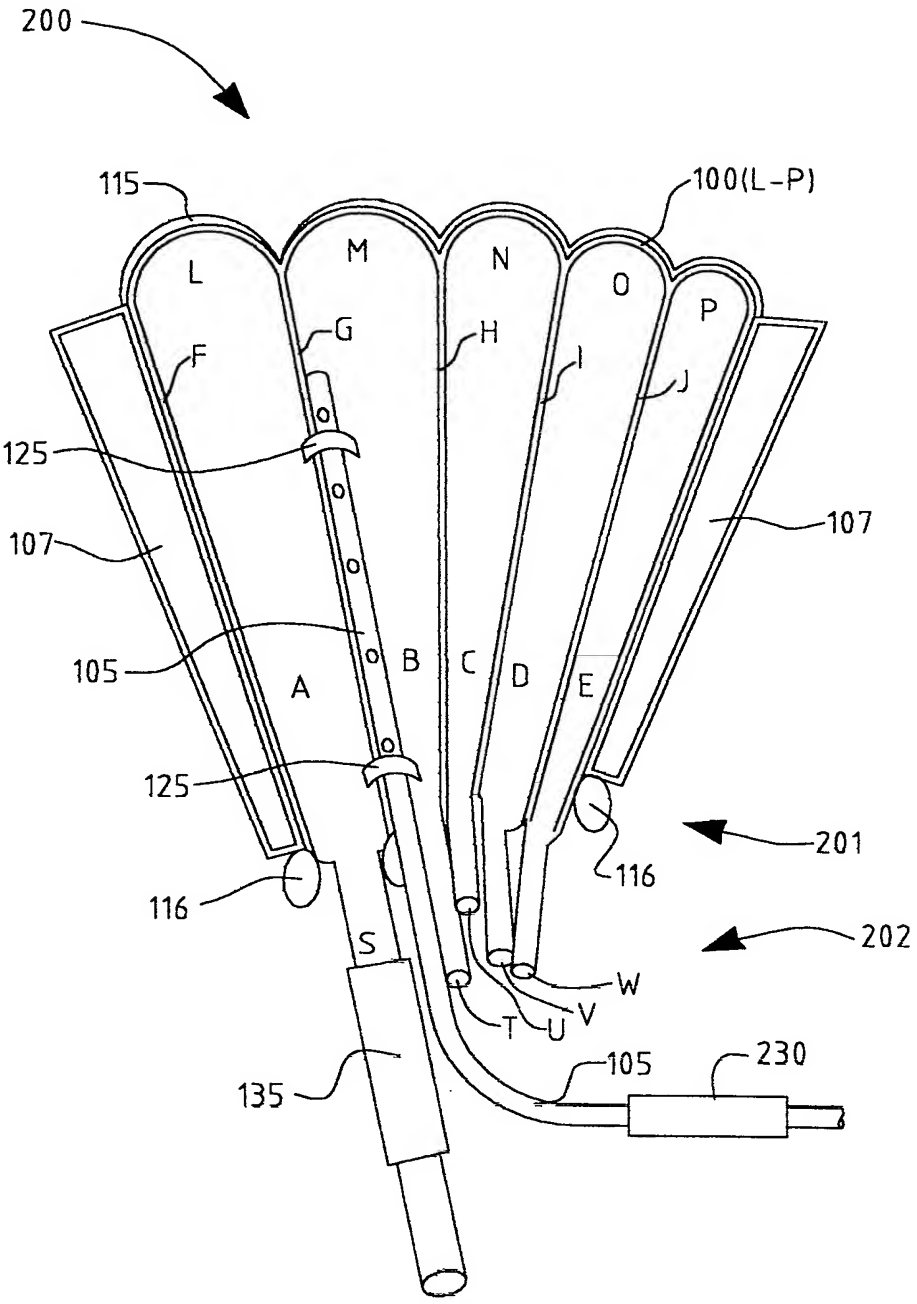

200
115
100(L-P)
L
M
N
O
P
F
G
H
I
J
125
107
107
105
A
B
C
D
E
125
201
116
116
202
S
W
T
U
V
105
230
135

Fig. 12

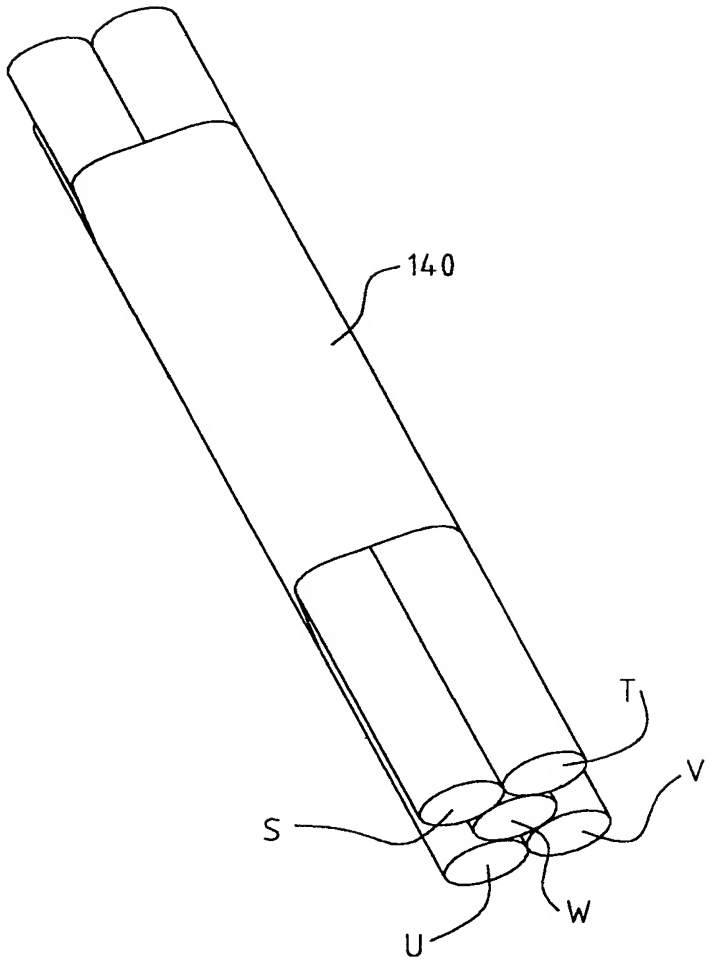


Fig. 13

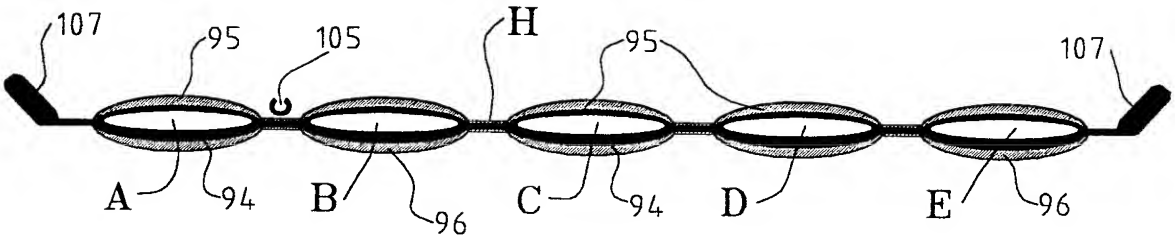


Fig. 14

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00433

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61M 1/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61B, A61M, A61H, A61K, A61N, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU IPC: A61M 1/10, 1/12

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT heart cardio ventric assist aid compress pump
JAPIO porous biointegrat attach hold graft membrane

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4048990 A (GOETZ) 20 September 1997 Figures 4 to 6, column 2 lines 12 to 27, Column 2 line 67 to column 3 line 27	1,4,6-10 19-21,27-29
Y	US 4957477 A (LUNDBACK) 18 September 1990 Column 4 line 41 - to column 4 line 64	1,4,6-10,13, 14, 19-21, 27-29
Y	US 5119804 A (ANSTADT) 9 June 1992 Column 5 line 2 to column 4 line 33	1,4,6-10,19-21 27-29

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 August 1998	19 AUG 1998
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	Authorized officer **MATTHEW FORWARD** Telephone No.: (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 98/00433

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5605693 A (SEARE) 25 February 1997 Column 1 lines 14 to 60, column 3 lines 48 to 67	1,4,6-10,13,14 19-21,27-29
Y	WO 96/11647 A (SEARE) 25 April 1996 Column 2 line 25 to column 3 line 16, Column 6 line 24 to column 7 line 6, Column 16 lines 15 to 23	1,4,6-10,13,14 19-21,27-29
P,A	US 5738627 A (KOVACS et al) 14 April 1998	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International Application No.
PCT/AU 98/00433

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	4957477	AU	73181/87	BR	8702612	CA	1325499
		CN	87103753	CS	8703722	DD	256451
		DK	2523/87	EP	247015	FI	872251
		HU	44181	IL	82566	IN	168344
		JP	62284644	NO	872108	NZ	220342
		PH	26007	PL	265810	PT	84916
		SE	8602335	ZA	8703539		
US	5119804	EP	603186	WO	9323004		
US	5605693	US	5589176	US	5624674	US	5681572
WO	9611647	CA	2202045	EP	786969	US	5759204
US	5738627	US	5749839				

END OF ANNEX